

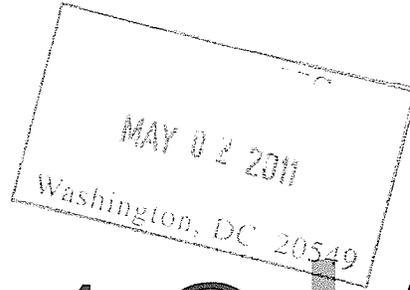


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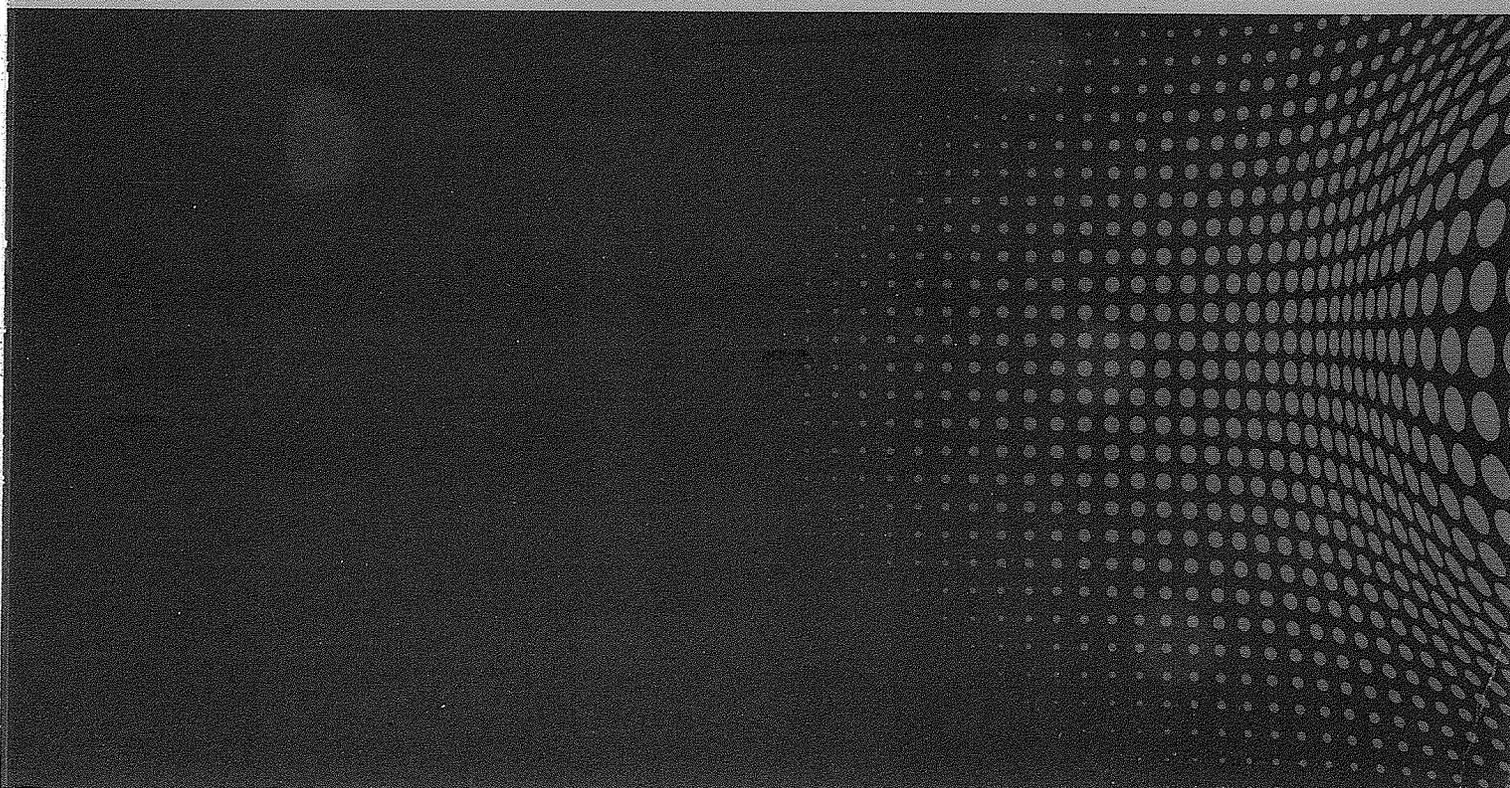
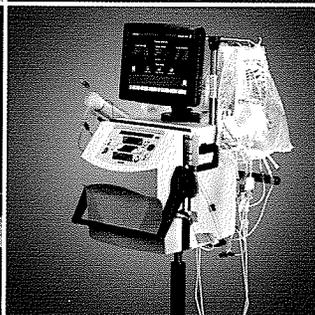
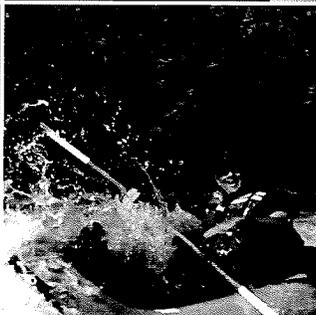
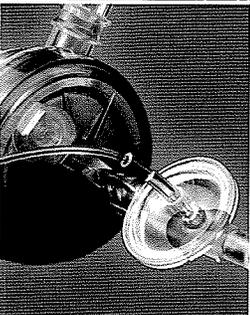
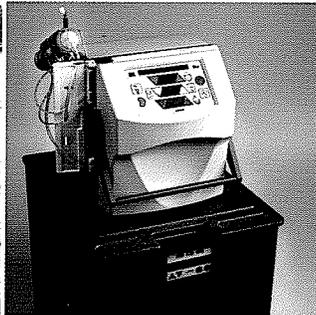
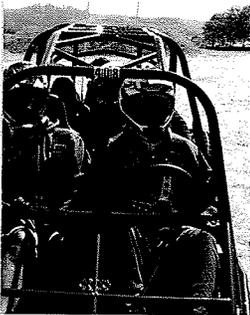


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2010 | Annual Report



Dear Shareholder,

NxStage® Medical delivered strong revenue growth in fiscal 2010 and continued to make meaningful progress in key areas across our business. This progress allowed us to achieve important financial and operational milestones during the year, ultimately solidifying our position as a technology leader in renal care and positioning us for continued growth.

Revenue for 2010 increased to \$179.2 million, representing 21% growth over 2009. In addition, we improved gross margin and achieved both positive adjusted EBITDA and positive cash flow for the year. We strengthened our balance sheet with \$73.4 million from our equity offering in November, and ended the fiscal year with cash and cash equivalents totaling \$104 million. Although we have not yet achieved profitable operating margins, we are encouraged by the improvements to our bottom line while continuing our investments in sales, marketing and research and development.

The Home Market

Home hemodialysis (HHD) remains our fastest growing business and also represents our largest market opportunity. We continue to pioneer this market with the NxStage System One™, the industry's only portable, easy-to-use home hemodialysis machine cleared by the FDA. By enabling more frequent HHD, the System One provides patients with ESRD access to the significant health and quality of life benefits possible with our therapy. Throughout 2010, continued systematic execution against our growth drivers for the Home drove the highest year of patient demand for HHD with NxStage. 2010 Home revenue grew an impressive 35% over 2009, as we expanded patient access to our therapy through new and existing relationships with service providers, including DaVita and Fresenius. We now have over 5,000 patients using the System One for HHD, and have done over 4 million treatments. We are very proud of this progress. Yet, with slightly more than 1% of the US dialysis market, HHD remains within the early stages of adoption and, despite strong clinical evidence in support of this therapy, many patients remain unaware of this option. We believe we are focused on the right drivers to continue developing this market. We remain committed to broadening patient access to the clinical and quality of life benefits possible with our life changing therapy and see significant growth opportunities moving forward.

The Critical Care Market

We are very pleased with the level of execution and performance in our critical care business throughout 2010. During the year, we continued to expand our technology leadership position in this market with new and existing customers embracing the System One for continuous renal replacement therapy. As a result, critical care revenue grew 26% in 2010 over 2009. Our critical care team's unwavering commitment to meeting our customers' needs and the distinct competitive advantages that we see with our product offering drove this growth and serves as a model for excellence across our Company.

Looking ahead, we're excited by critical care's growth potential. We have a large and growing installed base of customers that provides us with a highly predictable recurring disposable revenue stream, a strong competitive offering, and believe we have a healthy pipeline of opportunities for 2011 and beyond.

The In-center Market (Medisystems)

In 2010, we executed well and continued to solidify our leadership position within the in-center market, particularly with our Medisystems' high value, innovative products that include our ButtonHole® needle sets and Streamline®, our next generation blood tubing set. Moving forward, we continue to see opportunities to leverage our innovative product offerings with new and existing customers.

In summary, we made meaningful progress across our business in 2010, and clearly raised the bar on our performance. Entering 2011, we believe we have good underlying market fundamentals, a strong balance sheet, a solid operating model, as well as a culture of innovation. We are on a multi-year growth agenda and see significant opportunities across our business to advance our long term growth strategy.

I want to take this opportunity to thank all of our employees for their efforts, and to also recognize all our patients, their partners and providers for their continued support of NxStage. Leading the industry with innovative, safe and reliable products with superior customer service has been the hallmark of NxStage's mission and success. I am particularly pleased that, as we grow, we remain committed to these values as well as important clinical research for the benefit of patients with ESRD.

On behalf of NxStage, I extend my sincere thanks to you, our shareholders, for your continued support.

Sincerely,



Founder and Chief Executive Officer

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Form 10-K

(Mark One)

[X] ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

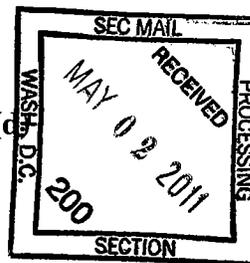
For the fiscal year ended December 31, 2010

OR

[] TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from to

Commission File Number: 000-51567



NxStage Medical, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware (State of Incorporation)

04-3454702 (I.R.S. Employer Identification No.)

439 S. Union St., 5th Floor, Lawrence, MA (Address of Principal Executive Offices)

01843 (Zip Code)

Registrant's telephone number, including area code: (978) 687-4700

Securities registered pursuant to Section 12(b) of the Act: Common Stock, \$0.001 par value

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes [X] No []

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes [] No [X]

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes [X] No []

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes [] No [X]

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. [X]

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer [] Accelerated filer [X] Non-accelerated filer [] Smaller reporting company [] (Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes [] No [X]

The aggregate market value of common stock held by non-affiliates of the registrant was approximately \$394.3 million, as of June 30, 2010, based on the last reported sale price of the registrant's common stock on the NASDAQ Global Select Market on June 30, 2010.

There were 53,751,518 shares of the registrant's common stock outstanding as of the close of business on February 14, 2011.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive Proxy Statement for its 2011 Annual Meeting of Stockholders to be held on May 26, 2011 are hereby incorporated by reference in response to Part III, Items 10, 11, 12, 13 and 14 of the Annual Report on Form 10-K.

NXSTAGE MEDICAL, INC.
2010 ANNUAL REPORT ON FORM 10-K
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CAUTIONARY NOTICE REGARDING FORWARD-LOOKING STATEMENTS

This report and certain information incorporated by reference herein contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, concerning our business, operations and financial condition, including statements with respect to the market adoption of our products in the United States and internationally; the growth of the home, critical care and in-center dialysis markets in general and the home hemodialysis market in particular; the development and commercialization of our products; changes in the historical purchasing patterns and preferences of our key customers, including DaVita Inc.; the adequacy of our funding; our ability to achieve and sustain positive cash flows; whether and when we might achieve improvements to our gross margins and operating expenses; expectations with respect to our operating expenses and achieving our business plan; expectations with respect to achieving profitable operations; expectations with respect to achieving improvements in product reliability; the timing and success of the submission, acceptance and approval of regulatory filings and the impact of any changes in the regulatory environment with respect to our products or business; the scope of patent protection with respect to our products; expectations with respect to the clinical findings of our FREEDOM study, and the impact of new and future changes to reimbursement for chronic dialysis treatments. All statements other than statements of historical facts included in this report regarding our strategies, prospects, financial condition, costs, plans and objectives are forward-looking statements. When used in this report, the words “expect”, “anticipate”, “intend”, “plan”, “believe”, “seek”, “estimate”, “potential”, “continue”, “predict”, “may”, and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Because these forward-looking statements involve risks and uncertainties, actual results could differ materially from those expressed or implied by these forward-looking statements for a number of important reasons, including those discussed below in “Risk Factors”, “Management’s Discussion and Analysis of Financial Condition and Results of Operations”, and elsewhere in this report.

You should read these forward-looking statements carefully because they discuss our expectations about our future performance, contain projections of our future operating results or our future financial condition or state other “forward-looking” information. You should be aware that the occurrence of any of the events described under “Risk Factors” and elsewhere in this report could substantially harm our business, results of operations and financial condition and that upon the occurrence of any of these events, the trading price of our common stock could decline.

We cannot guarantee future results, events, levels of activity, performance or achievements. The forward-looking statements contained in this report represent our expectations as of the date of this report and should not be relied upon as representing our expectations as of any other date. Subsequent events and developments will cause our expectations to change. However, while we may elect to update these forward-looking statements, we specifically disclaim any obligation to do so, even if our expectations change.

PART I

For convenience, in this Annual Report on Form 10-K, "NxStage," "we," "us," and "the Company" refer to NxStage Medical, Inc. and our consolidated subsidiaries, taken as a whole.

Item 1. Business

Overview

We are a medical device company that develops, manufactures and markets innovative products for the treatment of kidney failure, fluid overload and related blood treatments and procedures. Our primary product, the NxStage System One, or the System One, was designed to satisfy an unmet clinical need for a system that can deliver the therapeutic flexibility and clinical benefits associated with traditional dialysis machines in a smaller, portable, easy-to-use form that can be used by healthcare professionals and trained lay users alike in a variety of settings, including patient homes, as well as more traditional care settings such as hospitals and dialysis clinics. Given its design, the System One is particularly well-suited for home hemodialysis and a range of dialysis therapies including more frequent, or "daily," dialysis, which clinical literature suggests provides patients better clinical outcomes and improved quality of life. The System One is cleared or approved for commercial sale in the United States, Europe and Canada for the treatment of acute and chronic kidney failure and fluid overload. The System One is cleared specifically by the United States Food and Drug Administration, or FDA, for home hemodialysis as well as therapeutic plasma exchange, or TPE, in a clinical environment. We also sell needles and blood tubing sets primarily to dialysis clinics for the treatment of end-stage renal disease, or ESRD, which we refer to as the in-center market. We believe our largest future product market opportunity is for our System One used in the home hemodialysis market, or home market, for the treatment of ESRD using more frequent, or "daily" hemodialysis.

ESRD, which affects over 500,000 people in the United States and 2 million people worldwide, is an irreversible, life-threatening loss of kidney function that is treated predominantly with dialysis. Dialysis is a kidney replacement therapy that removes toxins and excess fluids from the bloodstream and, unless the patient receives a kidney transplant, is required for the remainder of the patient's life. Approximately, 70% of ESRD patients in the United States rely on life-sustaining dialysis treatment. Hemodialysis, the most widely prescribed type of dialysis, typically consists of treatments in a dialysis clinic three times per week, with each session lasting three to five hours. Approximately 8% of U.S. ESRD dialysis patients receive some form of dialysis treatment at home, most of whom treat themselves with peritoneal dialysis, or PD, although surveys of physicians and healthcare professionals suggest that a larger proportion of patients could take responsibility for their own care. Clinical data also suggests that hemodialysis therapy administered five or six times per week, commonly referred to as daily therapy, better mimics the natural functioning of the human kidney and can lead to improved clinical outcomes, including reductions in antihypertensive medications, reduced fluid overload, reduced depression and improvements in health-related quality of life. We believe there is an unmet need for a hemodialysis system that allows more frequent and easily administered therapy at home and have designed our system to address this and other kidney replacement markets. Currently, nearly all of our System One patients in the home market receive treatment between five or six times a week in order to take advantage of these reported clinical benefits.

Measuring 15x15x18 inches, the System One is the smallest commercially available hemodialysis system. It consists of a compact, portable and easy-to-use cyclor, disposable drop-in cartridge and high purity premixed fluid. The System One has a self-contained design and simple user interface making it easy to operate by a trained patient and his or her trained partner in any setting prescribed by the patient's physician. Unlike traditional dialysis systems, our System One does not require any special disinfection and its operation does not require specialized electrical or plumbing infrastructure or modifications to the home. Patients can bring the System One home, plug it in to a conventional electrical outlet and operate it, thereby eliminating what can be expensive plumbing and electrical household modifications required by other traditional dialysis systems. Because of its portability, patients also have the freedom to travel with the System One. We market the System One to dialysis clinics for chronic hemodialysis treatment. The clinics in turn provide the System One to ESRD patients.

We also market the System One to hospitals for treatment of acute kidney failure and fluid overload. It is estimated that there are over 200,000 cases of acute kidney failure in the United States each year. The clinical flexibility of our System One, coupled with its ease-of-use and portability, make our system well suited for hospital critical care environments.

In addition to the System One, we sell a line of extracorporeal disposable products for use primarily for in-center dialysis treatments for patients with ESRD. These products, which we obtained in connection with our October 2007 acquisition of Medisystems Corporation and certain affiliated entities, which we refer to collectively as Medisystems, include hemodialysis blood tubing sets, A.V. fistula needles and apheresis needles. Medisystems has been selling products to dialysis centers for the treatment of ESRD since 1981, and has achieved leading positions in the U.S. market for both hemodialysis blood tubing sets and AV fistula needles. Our blood tubing set products include the ReadySet High Performance Blood Tubing set, or ReadySet, and the Streamline Airless Blood Tubing set, or Streamline. ReadySet has been on the market since 1993. Streamline, our next generation product which was introduced in 2007, is designed to provide improved patient outcomes and lower costs to dialysis clinics. Our needle products line includes AV fistula needles incorporating safety features, first introduced in 1995, including PointGuard Anti-Stick Needle Protectors and MasterGuard technology, and ButtonHole needles, first introduced in 2002.

For the year ended December 31, 2010, our revenues were \$179.2 million and we incurred a net loss of \$31.7 million. As of December 31, 2010, we had cash and cash equivalents of \$104.3 million, total assets of \$286.1 million, long term liabilities of \$97.6 million and total stockholders' equity of \$152.1 million.

Since inception, we have incurred negative operating margins and losses every quarter. At December 31, 2010, we had an accumulated deficit of approximately \$308.4 million. While we have achieved positive gross margins for our products, in aggregate, since the fourth quarter of 2007, we cannot provide assurance that our gross margins will improve or, if they do improve, the rate at which they will improve. Continued improvements in gross margins are dependent on many factors, including growing revenues, reducing costs of revenues by implementing design and process improvements, obtaining better purchasing terms and prices and increasing reliability of our products. Additionally, we expect our operating expenses to continue to increase as we grow our business. Our ability to become profitable and, its timing and sustainability, depend principally upon continued improvements in gross margins, growing revenues, and leverage of our operating infrastructure including any investment in selling and marketing or research and development activities.

For the year ended December 31, 2010, cash flows from operating activities were positive due to improvements in net loss versus 2009 and a \$4.3 million one-time customer prepayment on first quarter 2011 orders. While we continue to make progress in improving our cash flows from operating activities, we expect cash flows from operating activities in the near term to fluctuate between negative and positive on a quarterly basis, primarily due to changes in working capital. There can be no assurance that we will be able to continue to improve cash flows from operating activities or whether we will be able to generate positive cash flows from operating activities in the future. We believe, based on current projections and the current nature of our business, that we have the required resources to fund our ongoing operating requirements. Our ability to and the rate at which we continue to improve cash flows from operating activities will depend on many factors, including growing revenues, continued improvements in gross margins, leverage of our operating infrastructure and continued sale versus rental of a significant percentage of our System One equipment.

We were incorporated in Delaware in 1998 under the name QB Medical, Inc., and later changed our name to NxStage Medical, Inc. Our principal executive offices are located at 439 South Union Street, Fifth Floor, Lawrence, Massachusetts 01843.

Additional financial information regarding our business segments and geographic data about our assets is contained in Management's Discussion and Analysis of Financial Condition and Results of Operations in Item 7 of Part II, and in our notes to Consolidated Financial Statements included in Item 8 of Part II of this Annual Report on Form 10-K.

Our Products and Services

The System One

Our primary product, the NxStage System One, is a small, portable, easy-to-use hemodialysis system. Sales of the System One and related disposables accounted for approximately 64%, 58% and 52% of our total sales for the years ended December 31, 2010, 2009 and 2008, respectively.

The System One includes the following components:

- *The NxStage Cycler.* A compact portable electromechanical device containing pumps, control mechanisms, safety sensors and remote data capture functionality.
- *The NxStage Cartridge.* A single-use, disposable, integrated treatment cartridge that loads simply and easily into the cycler. The cartridge incorporates a proprietary volumetric fluid management system and includes a pre-attached dialyzer.
- *Premixed Dialysate.* The System One uses high-purity premixed dialysate for hemodialysis applications. The volume of fluids used varies with treatment options, prescription, and setting. We supply our premixed dialysate in sterile five liter bags or through the use of our PureFlow SL accessory. The PureFlow SL module allows for the preparation of dialysate fluid in the patient's home using ordinary tap water and dialysate concentrate thereby reducing the need for bagged fluids for in-home treatments.

ReadySet

The ReadySet High Performance Blood Tubing Set, which was introduced for use in hemodialysis in 1993, features a pump segment material designed to deliver reliable, accurate flows throughout the treatment. The blood tubing is designed to be easy to handle and to enable relatively fast priming, or removal of air from the dialysate solution. These technological advances are intended to optimize dose delivery. Sales of ReadySet accounted for approximately 15%, 19% and 24% of our total sales for the years ended December 31, 2010, 2009 and 2008, respectively.

Streamline

Streamline, which was introduced in 2007, is our next generation blood tubing set product. Streamline features an efficient and airless design intended to result in superior clinical and economic performance and is designed to reduce treatment time, minimize waste and optimize dose delivery. Streamline also includes our patented LockSite needleless access sites, eliminating the need for sharp needles or costlier guarded needles to be used with the tubing set in connection with dialysis therapy, thereby intended to facilitate a clinician's ability to satisfy Occupational Safety and Health Administration, or OSHA, anti-stick requirements.

AV Fistula and Apheresis Needles

Our AV fistula and apheresis needles have been designed to achieve a smooth blood flow throughout the treatment, intended to result in less clotting, lower pressure drops, and less stress on the patient's blood. A significant amount of our needles sold are branded MasterGuard, and include our Fingershield® anchor designed to protect the operator from inadvertent needle stick injury. We also offer ButtonHole needles, first introduced in 2002, for hemodialysis therapies as an alternative to our AV fistula needles with MasterGuard. This needle is used by patients that employ "the constant-site technique", whereby a fistula needle is inserted in the same place each treatment. Published clinical experience suggests that the incidence of pain, hematoma, and infiltrations at the needle insertion site can be reduced by utilizing the constant-site technique. Our ButtonHole AV fistula needle has an anti-stick, dull bevel design well-suited for the constant-site technique, while also designed to reduce the risk of accidental needle sticks. Sales of needles accounted for approximately 12%, 14% and 18% of our total sales for the years ended December 31, 2010, 2009 and 2008, respectively.

Our Business by Segment

We report the results of our operations in two segments: System One and In-Center. We distribute our products in three markets: home, critical care and in-center. In the System One segment we derive our revenues from the sale and rental of equipment and the sale of disposable products in the home and critical care markets. We define the home market as the market devoted to the treatment of ESRD patients in the home and the critical care market as the market devoted to the treatment of hospital-based patients with acute kidney failure or fluid overload. In the In-Center segment, we derive our revenues from the sale of needles and blood tubing sets used predominantly in hemodialysis performed in-center as well as apheresis, which we refer to as the in-center market.

System One

We began marketing the System One to perform hemodialysis for ESRD patients in September 2004, and we began marketing our System One specifically for home use in July 2005, after the System One was cleared by the FDA for home hemodialysis. We market the System One to independent dialysis clinics as well as dialysis clinics that are part of national or regional chains, providing clinics with improved access to a developing market, the home hemodialysis market, and the ability to expand their patient base by adding home-based patients without adding clinic infrastructure. Since Medicare regulations require that all chronic ESRD patients be under the care of a dialysis clinic, whether they are treated at-home, in-clinic or with a kidney transplant, we do not sell the System One directly to patients.

For each month that a patient is treated with the System One, we bill the clinic for the purchase of the related disposable cartridges and treatment fluids necessary to perform treatment. A majority of our sales to customers in the home market include the purchase rather than the rental of System One equipment. Our two largest customers in the home market, DaVita and Fresenius, purchase rather than rent all or nearly all of their System One equipment.

After selling or renting a System One to a clinic, our clinical educators train the clinic's nurses and dialysis technicians on the proper use of the system using proprietary training materials. We are not responsible for, and do not provide patient training. We rely on our customers' trained technicians and nurses to train home patients, their partners and other technicians and nurses using the System One.

Patient training takes place at the clinic primarily during the patient's prescribed, often daily, two to three hour treatment sessions. Training typically takes two to three weeks and includes basic instruction on ESRD, the operation of the System One and the insertion by the patient or their partner of needles into the patient's vascular access site. Training sessions are presently reimbursed by Medicare or private insurance, and there may be a co-payment requirement to the patient associated with this training.

The System One cyler sold to hospitals in the critical care market is based on the same technology platform used in the home market, but includes an additional display module, called OneView, that is designed to facilitate easier medical record charting and troubleshooting. Most of our customers in the critical care market use our System to perform prolonged or continuous renal replacement therapy, also referred to as CRRT, for their acute kidney failure or fluid overload patients. We are specifically focusing our sales efforts in the critical care market on those large institutions that we believe are most dedicated to prolonged or continuous renal replacement therapy for patients with acute kidney failure and believe in ultrafiltration as an earlier-stage treatment option for fluid overload.

We primarily sell the System One cyler to customers in the critical care market; we also sell related disposable cartridges and treatment fluids necessary to perform dialysis treatment. After selling or renting a System One to a hospital, our clinical educators generally train the hospital's intensive care unit, or ICU, and acute dialysis nurses on the proper use of the System One using proprietary training materials. We then rely on the trained nurses to train other nurses. By adopting this "train the trainer" approach, our sales nurses do not need to return to the hospital each time a new nurse needs to be trained.

Ownership of United States dialysis clinics is highly consolidated. While there are over 5,500 Medicare-certified dialysis outpatient facilities in the United States, DaVita and Fresenius each control approximately

30% of U.S. dialysis market. Smaller chains and independent clinics and hospitals represent the approximately 40% of remaining clinics.

We sell or rent the System One to DaVita and a growing percentage of our System One sales are to Fresenius. DaVita is our most significant customer for the System One segment; with direct sales to DaVita representing approximately 34% of our System One segment revenues during 2010 and 38% and 35% during 2009 and 2008, respectively. Further, DaVita is our largest customer in the home market, constituting over 40% of our home hemodialysis patients. Our sales to Fresenius grew significantly in 2010, and Fresenius is now our second largest customer in the System One segment, with nearly all of those sales in the home market.

In July 2010, we entered into a First Amended and Restated National Service Provider Agreement, or the Amended Agreement, with DaVita expiring on June 30, 2013. The Amended Agreement supersedes our earlier agreement with DaVita entered into on February 7, 2007. Pursuant to the terms of the Amended Agreement, we agreed to continue to supply to DaVita the System One and PureFlow SL and related supplies for home hemodialysis therapy. Under the Amended Agreement, DaVita committed to continue to purchase, rather than rent, nearly all of its future System One equipment needs. After June 30, 2013, the term of the Amended Agreement may be automatically extended on a monthly basis unless terminated by either party pursuant to the Amended Agreement.

The Amended Agreement includes a modest increase to DaVita's pricing from the levels under the original 2007 agreement, and continues DaVita's right to receive most favored nations pricing for the System One and related supplies for home hemodialysis therapy, subject to certain requirements, including DaVita achieving certain System One home patient growth targets. In addition, under the Amended Agreement, DaVita is eligible for pricing discounts based upon the achievement of certain System One home patient growth targets (reflecting home patients who have remained on contiguous home hemodialysis therapy for at least three full months with the System One) at June 30, 2011, 2012 and 2013, and which further require DaVita to continue to grow its home patient census every six months during the term of the Amended Agreement. In order to conserve our cash, the pricing discount was structured to be paid as a warrant, in lieu of cash. The Amended Agreement provides for a range of warrant levels that may be earned based on DaVita and NxStage System One home patient targets. Under this tiered structure, DaVita would be required to grow its net patients on the NxStage System One at a compounded annual growth rate of approximately 20 percent from the level at the time of entering into the agreement in order to obtain any discount, while achieving the highest discount will require a significant increase above that. If all tiers of discounts are achieved, the Amended Agreement provides that DaVita may earn warrants to purchase up to 5.5 million shares of our common stock. The warrants have an exercise price of \$14.22 per share and are non-transferable and must be exercised in cash.

In connection with the issuance of the warrants, we entered into a Registration Rights Agreement with DaVita pursuant to which we agreed to file, on or prior to April 1, 2011, a registration statement on Form S-3 with respect to the resale by DaVita of any shares issued to DaVita under the warrant. We registered the shares of common stock issuable upon the exercise of the warrant on February 16, 2011 on our automatic shelf registration statement on Form S-3 filed on November 17, 2010 (No. 333-170654).

In-center

We sell primarily blood tubing sets and needles to customers in the in-center market. In this market, our customers are independent dialysis clinics as well as dialysis clinics that are part of national or regional chains. The majority of our sales in this market are made through distributors, in order to leverage national networks, shipping efficiencies and existing customer relationships. We plan our manufacturing and distribution activities based on distributor purchase orders. Finished goods are shipped directly to distributor warehouses. We support distributor selling and marketing efforts with brand marketing support and a team of clinical educators who assist with clinical in-service activities.

Our In-Center segment revenues are highly concentrated in several significant purchasers. Our two largest distributors are Henry Schein, Inc., or Henry Schein, and Gambro Renal Products, Inc., or Gambro. Revenues from Henry Schein represented approximately 44%, 66% and 80% of our In-Center segment revenues during

2010, 2009 and 2008, respectively. Revenues from Gambro represented approximately 36% and 14% of our In-Center segment revenues during 2010 and 2009, respectively. Gambro was not a distributor of ours in 2008. Our distribution agreement with Henry Schein will expire in April 2012. Our distribution agreement with Gambro will expire in July 2014.

Sales of our products through distributors to DaVita accounted for nearly half of In-Center segment revenues during 2010, 2009 and 2008. DaVita has contractual purchase commitments under two agreements: one with us for needles and one with Gambro for blood tubing sets. DaVita's contractual purchase obligations with respect to needles will expire in January 2013. Gambro's long term product supply agreement with DaVita entered into in connection with the sale of Gambro's United States dialysis clinic business to DaVita in 2005, obligates DaVita to purchase a significant majority of its blood tubing set requirements from Gambro through 2015. In June 2009, we entered into a five year distribution agreement in the United States with Gambro, which contractually obligates Gambro to exclusively supply our blood tubing sets, including our ReadySet and the Streamline product lines, to DaVita through July 2014.

International

Historically, we have focused nearly all of our sales and marketing efforts in the United States. In 2009 we began entering into arrangements with distributors to sell the System One and certain of our other products internationally. Currently, we have distribution arrangements with several international partners for the sale of our System One in Europe and the Middle East. Finished goods are shipped directly to distributor warehouses. The distributors sell or rent our products to dialysis providers or hospitals. Currently, distributors handle marketing, patient and clinic training and equipment servicing and repair. To date, our international sales have been quite limited, and we are still very early in our international commercialization efforts.

Marketing, Customer Support

We have a sales force that calls on dialysis clinics, nephrologists and hospitals. In addition to specialized sales representatives, we also employ nurses in our sales force as clinical educators to support our sales efforts. We have a staff of Customer Support Specialists to assist patients, clinics and hospitals with product orders and deliveries, and also provide technical support 24-hours a day, seven days a week through a dedicated staff of Technical Support Representatives, to respond to questions raised by patients, clinics and hospitals concerning the System One. Our direct sales efforts focus almost exclusively on the home and critical care markets as we rely heavily on distributors to sell our products in the in-center market.

In the home market we primarily use a depot service model for equipment servicing and repair while we generally service equipment sold to customers in the critical care market in the field. For our home market customers, if a device requires repair, we arrange for a replacement device to be shipped to the site of care, whether it is a patient's home, clinic or hospital, and for pick up and return to us of the system requiring service. This shipment is done by common carrier, and, as there are no special installation requirements, the patient, clinic or hospital can quickly and easily set up the new machine. The nature of the hospital critical care settings, coupled with the practices of other ICU dialysis equipment suppliers, necessitates an option for on-site support for our systems installed in this environment.

Competition

The dialysis therapy market is mature, consolidated and competitive. Our System One in the critical care market competes against Gambro, Fresenius Medical Care AG, Baxter Healthcare, or Baxter, B. Braun and others. Our product lines in the in-center market compete directly against products produced by Fresenius Medical Care AG, Gambro, Nipro, B. Braun, Baxter Healthcare, JMS and others. Our competitors each market one or more FDA-cleared medical devices for the treatment of acute or chronic kidney failure. Each of these competitors offer products that have been in use for a longer time than our System One and are more widely recognized by physicians, patients and providers. These competitors have significantly more financial and human resources, more established sales and distribution channels, service and customer support infrastructures and spend more on product development and marketing than we do. Many of our competitors also have

established relationships with the providers of dialysis therapy and, Fresenius owns and operates a chain of dialysis clinics. The product lines of most of these companies are broader than ours, enabling them to offer a broader bundle of products that may afford them a significant competitive advantage.

We believe the competition in the market for kidney dialysis equipment and supplies is based primarily on:

- product quality;
- ease-of-use;
- cost effectiveness;
- sales force coverage; and
- clinical flexibility and performance.

We presently have the only portable product specifically cleared for home hemodialysis therapy in the United States. However, on February 18, 2011, we learned that Fresenius, our second largest customer in the System One segment, with nearly all of these sales in the home market, obtained in February 2011 clearance to use its 2008K At Home hemodialysis system for use in home chronic therapy. There is also an increasing interest in the home hemodialysis market from other competitors. Baxter has a research and development collaboration with DEKA Research and Development Corporation and HHD, LLC, or DEKA, and has recently indicated that it received Investigation Device Exemption, or IDE, approval from the FDA and hopes to commence U.S. and Canadian clinical studies of DEKA's new home hemodialysis system in 2011 and launch in international markets as early as 2011 and obtain regulatory approval for Europe in 2012. Other small companies are also working to develop products for this market. We are unable to predict when, if ever, any of these products may attain regulatory clearance and appear in the market, or how successful they may be should they be introduced, but if additional viable products are introduced to the market, it could adversely affect our sales and growth.

For the critical care market, we believe we compete favorably in terms of product quality and ease of use due to our System One design, portability, drop-in cartridge and use of premixed fluids. We believe we also compete favorably on the basis of clinical flexibility, given the System One's ability to perform hemofiltration, hemodialysis and ultrafiltration. However, the fact that we are not indicated for hemodiafiltration may be perceived by some clinicians as a disadvantage of our system over others. We believe we compete favorably in terms of cost-effectiveness for hospitals that perform continuous renal replacement therapies, or CRRT. In the fluid overload market, which is a very small component of our critical care market, drug therapy is currently the most common and preferred treatment. To date, ultrafiltration has not been broadly adopted and, if the medical community does not accept ultrafiltration as clinically useful, cost-effective and safe, we will not be able to successfully compete against existing pharmaceutical therapies in the treatment of fluid overload.

For the in-center market, where we sell needles and blood tubing sets, we believe that we compete favorably in terms of product quality, ease-of-use, cost effectiveness, clinical flexibility and performance. We also compete favorably in terms of branding, as Medisystems has been selling products to dialysis centers for the treatment of ESRD since 1981. We compete unfavorably in terms of sales force coverage, as we rely nearly exclusively on distributors, rather than our own direct sales force.

Our primary competitors are large, well-established businesses with significantly more financial and personnel resources and greater commercial infrastructures than us. We believe our ability to compete successfully will depend largely on our ability to:

- establish the infrastructures necessary to support a growing home, critical care and in-center dialysis products business;
- maintain and improve product quality;
- continue to develop sales and marketing capabilities;
- continuously improve our products and develop and obtain clearance for new products; and
- achieve cost reductions.

Our ability to successfully market our products for the treatment of kidney failure could also be adversely affected by pharmacological and technological advances in preventing the progression of chronic ESRD and/or in the treatment of acute kidney failure, technological developments by others in the area of dialysis, the development of new medications designed to reduce the incidence of kidney transplant rejection and progress in using kidneys harvested from genetically-engineered animals as a source of transplants. There can be no assurance that competitive pressure or pharmacological or technological advancements will not have a material adverse effect on our business.

Clinical Experience and Results

Over 100 published articles have reported on the benefits of daily dialysis therapy. Although many of these publications were based on studies that did not use our product, the literature strongly supports that daily hemodialysis therapy can lead to improved clinical outcomes, including reduction in left ventricular mass, reduction in hypertension and use of antihypertensive medications, improved nutritional status, and overall improvement in quality of life, including improvements related to overall physical and mental health, depressive symptoms, sleep, restless legs syndrome and post-dialysis recovery time.

In early 2006, we enrolled the first patient in our post-market FREEDOM (Following Rehabilitation, Economics, and Everyday Dialysis Outcome Measurements) study, which is designed to quantify the clinical and economic benefits of daily home therapy administered to Medicare patients with the System One versus conventional thrice-weekly dialysis. The FREEDOM study is a prospective, multi-center, observational study, which will enroll up to 500 Medicare patients in up to 70 clinical centers. Enrollment is ongoing. The study will compare Medicare patients using the System One with a matched cohort of patients from the United States Renal Data System, or USRDS, patient database treated with traditional in-center thrice weekly dialysis, to help define differences in the cost of care and patient outcomes between the daily home setting and the dialysis clinic setting. Comparing the study group of patients using the System One to a USRDS database group matched in terms of demographics, co-morbidities, geography, number of years on dialysis and other key factors, should allow a valuable comparison to be made without the time and cost challenges of a crossover study, in which patients would be followed for a given time on each type of therapy.

Our goal is to provide further insights into more frequent dialysis and its cost-effectiveness as well as to confirm the significant reported potential benefits of daily therapy on patient quality of life and rehabilitation. Published U.S. government data estimates the total health care cost burden of a Medicare dialysis patient at over \$70,000 annually, with dialysis services representing approximately 25% of this cost, while the cost of hospitalizations, drugs and physician fees make up nearly 60%.

Interim four and twelve month results from our ongoing FREEDOM study show daily home hemodialysis treatment made possible by the System One therapy significantly improves select measures of patient quality-of-life as compared to conventional, thrice-weekly in-center treatment. Specific improvements identified to date include a reduction in post dialysis recovery time (the average time to resume normal activity), returning significant quality time to patients each week. Other benefits include a reduction in depressive symptoms, improvements in select physical and mental health quality of life domains, a reduction in antihypertensive medications, improvements in sleep and restless legs syndrome.

We also completed an approved IDE study intended to support a home nocturnal indication for the System One. Enrollment started in the first quarter of 2008 and we submitted the associated 510(k) to the FDA in 2010. We met our primary safety and efficacy endpoints for the study. Nevertheless, the FDA recently notified us that their standards for what will be required for a home nocturnal clearance may change from what was required in our approved IDE. We continue to discuss with the FDA what the pathway to clearance for our product should be, and are evaluating our next steps.

In addition to the FREEDOM and nocturnal studies, we have completed two significant clinical trials with the System One for ESRD therapy, a post-market study of chronic daily hemofiltration and a study under an FDA-approved IDE. We have also completed a study of ultrafiltration with the System One for fluid overload associated with Congestive Heart Failure, or CHF.

In the IDE study, we compared center-based and home-based daily dialysis with the System One. That study was a prospective, multi-center, two-treatment, two-period, open-label, cross-over study. The first phase of the study consisted of 48 treatments, six per week, in an eight-week period performed in-center, while the second phase consisted of the same number of treatments performed in an in-home setting. Between the two phases, there was a two-week transition period conducted primarily in the patient's home. Prior to study initiation, enrolled patients were to have been on at least two weeks of daily hemodialysis with the System One in an in-center environment. The objective of the study was to evaluate equivalence on a per-treatment basis between the delivery of hemodialysis with our system in-center and at home. The result of the investigation showed that the safety and effectiveness of hemodialysis with our system in each setting was equivalent.

Research and Development

Our research and development organization has focused on developing innovative technical approaches that address the limitations of current dialysis systems and disposable products. Our development team has skills across the range of technologies required to develop and maintain dialysis systems and products. These areas include filters, tubing sets, mechanical systems, fluids, software and electronics. In response to physician and patient feedback and our own assessments, we are continually working on enhancements to our product designs to improve ease-of-use, functionality, reliability and safety and to reduce product cost. We also seek to develop new products that supplement our existing product offerings and intend to continue to actively pursue opportunities for the research and development of complementary products.

For the years ended December 31, 2010, 2009 and 2008, we incurred research and development expenses of \$12.9 million, \$9.8 million and \$8.9 million, respectively.

Intellectual Property

We seek to protect our investment in the research, development, manufacturing and marketing of our products through the use of patent, trademark, copyright and trade secret law. We own or have licensed rights to a number of patents, trademark, copyrights, trade secrets and other intellectual property directly related and important to our business both in the United States and abroad. We also have domestic and foreign pending patent applications.

As of December 31, 2010, we had 85 issued U.S. and international patents, 1 issued European Union, or EU, industrial design registration and 32 U.S., international and foreign pending patent applications.

<u>Patent No.</u>	<u>Regime</u>	<u>Title</u>	<u>Issue Date</u>	<u>Expiration Date</u>
09/512,132	US	FLOW-THROUGH PERITONEAL DIALYZER SYSTEM AND METHODS WITH ON-LINE DIALYSIS SOLUTION REGENERATION	7/3/2001	2/23/2020
09/513,902	US	LAYERED FLUID CIRCUIT ASSEMBLIES AND METHODS FOR MAKING THEM	4/29/2003	2/14/2017
09/829,670	US	DEVICES FOR WARMING FLUID AND METHODS OF USE	6/3/2003	4/9/2021
09/900,362	US	METHOD AND APPARATUS FOR LEAK DETECTION IN A FLUID LINE	6/3/2003	7/7/2021
09/513,773	US	FLUID PROCESSING SYSTEMS AND METHODS USING EXTRACORPOREAL FLUID FLOW PANELS ORIENTED WITHIN A CARTRIDGE	6/17/2003	2/25/2020
09/027,301	US	HEMOFILTRATION SYSTEM INCLUDING ULTRAFILTRATE PURIFICATION AND RE-INFUSION SYSTEM	6/24/2003	2/20/2018

<u>Patent No.</u>	<u>Regime</u>	<u>Title</u>	<u>Issue Date</u>	<u>Expiration Date</u>
09/512,927	US	EXTRACORPOREAL CIRCUITS FOR PERFORMING HEMOFILTRATION EMPLOYING PRESSURE SENSING WITHOUT AN AIR INTERFACE	7/8/2003	2/14/2017
09/513,915	US	SYSTEMS AND METHODS FOR CONTROLLING BLOOD FLOW AND WASTE FLUID REMOVAL DURING HEMOFILTRATION	7/22/2003	2/14/2017
09/513,911	US	SYNCHRONIZED VOLUMETRIC FLUID BALANCING SYSTEMS AND METHODS	10/28/2003	2/14/2017
09/512,929	US	FLUID REPLACEMENT SYSTEMS AND METHODS FOR USE IN HEMOFILTRATION	10/28/2003	2/25/2020
09/905,246	US	METHOD FOR PERFORMING RENAL REPLACEMENT THERAPY INCLUDING PRODUCING STERILE REPLACEMENT FLUID IN A RENAL REPLACEMENT THERAPY UNIT	11/18/2003	7/12/2021
09/513,771	US	INTERACTIVE SYSTEMS AND METHODS FOR SUPPORTING HEMOFILTRATION THERAPIES	1/6/2004	2/14/2017
09/904,712	US	DEVICES AND METHODS FOR POTTING A FILTER FOR BLOOD PROCESSING	3/9/2004	7/12/2021
09/907,872	US	HERMETIC FLOW SELECTOR VALVE	6/1/2004	7/17/2021
09/513,910	US	BLOOD TREATMENT SYSTEMS AND METHODS THAT MAINTAIN STERILE EXTRACORPOREAL FLUID PROCESSING SYSTEMS AND METHODS USING	12/14/2004	2/14/2017
09/865,905	US	EXTRACORPOREAL FLUID FLOW METHOD AND APPARATUS FOR MANUFACTURING FILTERS	2/8/2005	2/14/2017
10/393,295	US	HEMOFILTRATION SYSTEM	3/29/2005	3/20/2023
09/894,236	US	SYSTEMS AND METHODS FOR PERFORMING BLOOD PROCESSING AND/OR FLUID EXCHANGE PROCEDURES	10/18/2005	2/14/2017
10/041,949	US		12/27/2005	2/14/2017
09/174,721	US	METHODS, SYSTEMS, AND KITS FOR THE EXTRACORPOREAL PROCESSING OF BLOOD	2/28/2006	2/11/2018
10/037,429	US	METHOD AND APPARATUS FOR LEAK DETECTION IN BLOOD CIRCUITS COMBINING EXTERNAL FLUID DETECTION AND AIR INFILTRATION DETECTION	5/9/2006	1/4/2022
10/483,142	US	METHOD AND APPARATUS FOR LEAK DETECTION IN A FLUID LINE	8/8/2006	7/9/2024
10/672,242	US	Volumetric fluid balance control for extracorporeal blood treatment	9/26/2006	9/26/2023
10/796,787	US	MEASUREMENT OF FLUID PRESSURE IN A BLOOD TREATMENT DEVICE	12/12/2006	2/14/2017

<u>Patent No.</u>	<u>Regime</u>	<u>Title</u>	<u>Issue Date</u>	<u>Expiration Date</u>
10/650,935	US	FLUID CIRCUITS, SYSTEMS, AND PROCESSES FOR EXTRACORPOREAL BLOOD PROCESSING	5/8/2007	7/12/2021
10/772,888	US	FLUID PROCESSING APPARATUS	6/5/2007	7/13/2021
10/808,213	US	Renal replacement therapy device for controlling fluid balance of treated patient	9/11/2007	2/24/2018
10/807,906	US	BLOOD PROCESSING MACHINE AND SYSTEM USING FLUID CIRCUIT CARTRIDGE	11/27/2007	5/4/2021
10/808,207	US	BLOOD PROCESSING MACHINE FLUID CIRCUIT CARTRIDGE	3/4/2008	6/9/2018
11/160,586	US	PRESSURE DETECTOR FOR FLUID CIRCUITS	3/4/2008	6/14/2024
10/913,815	US	Modular medical treatment replaceable component	3/25/2008	6/30/2018
11/695,739	US	FLUID, CIRCUITS, SYSTEMS, AND PROCESSES FOR EXTRACORPOREAL BLOOD PROCESSING	9/2/2008	7/12/2021
10/393,185	US	DUAL ACCESS SPIKE FOR INFUSATE BAGS	12/30/2008	1/11/2024
10/649,582	US	Hemofiltration systems and methods that maintain sterile extracorporeal processing conditions	1/6/2009	8/11/2020
11/160,764	US	BATCH FILTRATION SYSTEM FOR PREPARATION OF STERILE FLUID FOR RENAL REPLACEMENT THERAPY	6/9/2009	1/7/2024
11/742,715	US	SYSTEMS AND METHODS FOR HANDLING AIR AND/OR FLUSHING FLUIDS IN A FLUID CIRCUIT	9/15/2009	7/13/2021
10/544,124	US	WASTE BALANCING FOR EXTRACORPOREAL BLOOD TREATMENT SYSTEMS	3/30/2010	7/7/2026
12/434,246	US	BATCH FILTRATION SYSTEM FOR PREPARATION OF STERILE FLUID FOR RENAL REPLACEMENT THERAPY	7/6/2010	1/7/2024
11/951,142	US	FLUID LINE CONNECTOR SAFETY DEVICE	7/20/2010	5/5/2028
10/699,921	US	FUNCTIONAL ISOLATION OF UPGRADEABLE COMPONENTS TO REDUCE RISK IN MEDICAL TREATMENT DEVICES	8/10/2010	2/4/2023
10/796,913	US	REGISTRATION OF FLUID CIRCUIT COMPONENTS IN A BLOOD TREATMENT DEVICE	8/17/2010	10/28/2023
12/015,420	US	METHODS, DEVICES, AND SYSTEMS FOR HEMODILUTION	8/17/2010	8/11/2021
12/021,872	US	BLOOD TREATMENT APPARATUS	8/24/2010	2/14/2017
12/508,900	US	SYSTEMS AND METHODS FOR HANDLING AIR AND/OR FLUSHING FLUIDS IN A FLUID CIRCUIT	9/7/2010	7/13/2021

<u>Patent No.</u>	<u>Regime</u>	<u>Title</u>	<u>Issue Date</u>	<u>Expiration Date</u>
2003-512663	JP	METHOD AND APPARATUS FOR LEAK DETECTION IN A FLUID LINE	5/2/2008	7/8/2022
2001-543177	JP	LAYERED FLUID CIRCUIT ASSEMBLIES AND METHODS FOR MAKING THEM	10/9/2009	11/29/2020
2001-539403	JP	FLUID PROCESSING SYSTEMS AND METHODS USING EXTRACORPOREAL FLUID FLOW PANELS ORIENTED WITHIN A CARTRIDGE	12/4/2009	11/29/2020
2006-538506	JP	IMPROVED METHODS AND APPARATUS FOR LEAK DETECTION IN BLOOD PROCESSING SYSTEMS	12/4/2009	11/5/2024
04757998.2	IT	METHOD AND APPARATUS FOR MANUFACTURING FILTERS [2006/10]	3/10/2010	3/19/2024
07760334.8	IT	TUBING CLAMP FOR MEDICAL APPLICATIONS	8/11/2010	4/9/2027
04810398.0	IT	APPARATUS FOR LEAK DETECTION IN BLOOD PROCESSING SYSTEM	9/8/2010	11/5/2024
02761044.3	IT	METHOD AND APPARATUS FOR LEAK DETECTION IN A FLUID LINE	9/8/2010	7/8/2022
06717769.1	IT	FILTRATION SYSTEM FOR PREPARATION OF FLUIDS FOR MEDICAL APPLICATIONS	10/20/2010	1/9/2026
00991516.6	IT	FLUID PROCESSING SYSTEMS AND METHODS USING EXTRACORPOREAL FLUID FLOW PANELS ORIENTED WITHIN A CARTRIDGE	2/9/2011	11/29/2020
98904867.3	GB	HEMOFILTRATION SYSTEM	11/16/2005	2/5/2018
04700648.1	GB	PREPARING REPLACEMENT FLUID	6/24/2009	1/7/2024
00982268.5	GB	SYNCHRONIZED VOLUMETRIC FLUID BALANCING SYSTEMS AND METHODS	1/13/2010	11/29/2020
04757998.2	GB	METHOD AND APPARATUS FOR MANUFACTURING FILTERS [2006/10]	3/10/2010	3/19/2024
07760334.8	GB	TUBING CLAMP FOR MEDICAL APPLICATIONS	8/11/2010	4/9/2027
04810398.0	GB	APPARATUS FOR LEAK DETECTION IN BLOOD PROCESSING SYSTEM	9/8/2010	11/5/2024
02761044.3	GB	METHOD AND APPARATUS FOR LEAK DETECTION IN A FLUID LINE	9/8/2010	7/8/2022
06717769.1	GB	FILTRATION SYSTEM FOR PREPARATION OF FLUIDS FOR MEDICAL APPLICATIONS	10/20/2010	1/9/2026

<u>Patent No.</u>	<u>Regime</u>	<u>Title</u>	<u>Issue Date</u>	<u>Expiration Date</u>
00991516.6	GB	FLUID PROCESSING SYSTEMS AND METHODS USING EXTRACORPOREAL FLUID FLOW PANELS ORIENTED WITHIN A CARTRIDGE	2/9/2011	11/29/2020
04757998.2	FR	METHOD AND APPARATUS FOR MANUFACTURING FILTERS [2006/10]	3/10/2010	3/19/2024
07760334.8	FR	TUBING CLAMP FOR MEDICAL APPLICATIONS	8/11/2010	4/9/2027
04810398.0	FR	APPARATUS FOR LEAK DETECTION IN BLOOD PROCESSING SYSTEM	9/8/2010	11/5/2024
02761044.3	FR	METHOD AND APPARATUS FOR LEAK DETECTION IN A FLUID LINE	9/8/2010	7/8/2022
06717769.1	FR	FILTRATION SYSTEM FOR PREPARATION OF FLUIDS FOR MEDICAL APPLICATIONS	10/20/2010	1/9/2026
00991516.6	FR	FLUID PROCESSING SYSTEMS AND METHODS USING EXTRACORPOREAL FLUID FLOW PANELS ORIENTED WITHIN A CARTRIDGE	2/9/2011	11/29/2020
000023148-0001	EU	BLOOD TREATMENT MACHINE AND PARTS THEREOF	4/1/2003	4/1/2028
04700648.1	DE	PREPARING REPLACEMENT FLUID	6/24/2009	1/7/2024
60043710.8-08	DE	SYNCHRONIZED VOLUMETRIC FLUID BALANCING SYSTEMS AND METHODS	1/13/2010	11/29/2020
602004 025 923.3-08	DE	METHOD AND APPARATUS FOR MANUFACTURING FILTERS [2006/10]	3/10/2010	3/19/2024
602007008395.8	DE	TUBING CLAMP FOR MEDICAL APPLICATIONS	8/11/2010	4/9/2027
602004029077.7	DE	APPARATUS FOR LEAK DETECTION IN BLOOD PROCESSING SYSTEM	9/8/2010	11/5/2024
60237621.1	DE	METHOD AND APPARATUS FOR LEAK DETECTION IN A FLUID LINE	9/8/2010	7/8/2022
602006017654.6	DE	FILTRATION SYSTEM FOR PREPARATION OF FLUIDS FOR MEDICAL APPLICATIONS	10/20/2010	1/9/2026
N/A	DE	FLUID PROCESSING SYSTEMS AND METHODS USING EXTRACORPOREAL FLUID FLOW PANELS ORIENTED WITHIN A CARTRIDGE	2/9/2011	11/29/2020
2,593,580	CA	FILTRATION SYSTEM FOR PREPARATION OF FLUIDS FOR MEDICAL APPLICATIONS	11/23/2010	1/9/2026

* EU industrial design registration

Patents for individual products extend for varying periods of time according to the date a patent application is filed or a patent is granted and the term of the patent protection available in the jurisdiction granting the patent. The scope of protection provided by a patent can vary significantly from country to country.

In connection with the acquisition of Medisystems on October 1, 2007, we also acquired exclusive license rights to a portfolio of patents from Lifestream Medical Corporation (formerly known as DSU Medical Corporation). Lifestream Medical Corporation is wholly-owned by David S. Utterberg, a member of our board of directors and a significant stockholder of the Company. On February 17, 2011, Lifestream Medical Corporation assigned the formerly licensed patents to us, giving us control over the prosecution and maintenance of such patents and the ability to operate under such patents in all fields for any purpose. The assignment agreement does, however, provide that our rights under the patents are qualified by certain sublicenses previously granted to third parties. We have agreed that Mr. Utterberg will retain the right to royalty income under one of these sublicenses.

The following table lists all of the licensed patents assigned to us, by Lifestream Medical Corporation.

<u>Patent No.</u>	<u>Regime</u>	<u>Title</u>	<u>Issue Date</u>	<u>Expiration Date</u>
5643190	US	Flow-Through Treatment Device	7/1/1997	1/17/2015
5328461	US	Blow Molded Venous Drip Chamber For Hemodialysis	7/12/1994	7/12/2011
5330425	US	Blow Molded Venous Drip Chamber For Hemodialysis	7/19/1994	4/30/2012
5360395	US	Pump Conduit Segment Having Connected, Parallel Branch Line	11/1/1994	12/20/2013
5520640	US	Blood Air Trap Chamber	5/28/1996	5/28/2013
5772638	US	Protector For Needle	6/30/1998	9/17/2016
5772624	US	Reusable Blood Lines	6/30/1998	7/20/2015
5817043	US	Flow-Through Treatment Device	10/6/1998	1/17/2015
5895368	US	Blood Set Priming Method And Apparatus	4/20/1999	9/23/2016
6440095	US	Pump Segment Having Connected Parallel Branch Line	8/27/2002	12/31/2015
6165149	US	Reusable Blood Lines	12/26/2000	7/20/2015
5951870	US	Automatic Priming Of Blood Sets	9/14/1999	10/21/2017
5824213	US	Separable Hemodialysis System	10/20/1998	9/7/2014
5895571	US	Separable Hemodialysis System Connected By A Movable Arm	4/20/1999	9/7/2014
6299589	US	Flow-Through Treatment Method	10/9/2001	1/17/2015
6290665	US	Blood Set Priming Method And Apparatus	9/18/2001	9/23/2016
6177049	US	Reversing Flow Blood Processing System	1/23/2001	6/10/2018
5980741	US	Bubble Trap With Flat Side Having Multipurpose Supplemental Ports	11/9/1999	8/1/2017
6010623	US	Bubble Trap With Flat Side	1/4/2000	8/1/2017
6019824	US	Bubble Trap Chamber	2/1/2000	6/9/2018
6117342	US	Bubble Trap With Directed Horizontal Flow And Method Of Using	9/12/2000	11/26/2016
6755801	US	Dialysis Pressure Monitoring With Clot Suppression	6/29/2004	11/8/2019
6319465	US	Reversing Flow Blood Processing System Having Reduced Clotting Potential	11/20/2001	6/3/2019
6387069	US	Blood Set Priming Method And Apparatus	5/14/2002	9/23/2016
6051134	US	Bubble Trap Having Common Inlet/Outlet Tube	4/18/2000	3/28/2017
6187198	US	Automatic Priming Of Connected Blood Sets	2/13/2001	10/21/2017
6517508	US	Set For Blood Processing	2/11/2003	11/3/2019
6206954	US	Blood Set And Chamber	3/27/2001	5/13/2018
4501729	JP	Automatic Priming Of Blood Sets	5/1/2001	10/13/2018
2306829	CA	Automatic Priming Of Blood Sets	5/1/2007	10/13/2018
743310	AU	Automatic Priming Of Blood Sets	5/9/2002	10/13/2018

<u>Patent No.</u>	<u>Regime</u>	<u>Title</u>	<u>Issue Date</u>	<u>Expiration Date</u>
6344139	US	Arterial And Venous Blood Tubing Set	2/5/2002	10/21/2017
7025750	US	Set For Blood Processing	4/11/2006	1/7/2020
6596234	US	Reversing Flow Blood Processing System	7/22/2003	3/14/2019
6620119	US	Reusable Blood Lines	9/16/2003	11/12/2015
6464878	US	Automatic Priming Of Blood Sets	10/15/2002	10/21/2017
6695807	US	Blood Flow Reversing System	2/24/2004	1/18/2022
7166084	US	Blood Set Priming Method And Apparatus	1/23/2007	7/22/2017
6666839	US	Method of Using Reusable Blood Lines	12/23/2003	7/20/2015
5983947	US	Docking Ports For Medical Fluid Sets	11/16/1999	3/3/2017
4117505	JP	Flow-Trough Treatment Device	5/2/2008	7/17/2017
3103938	JP	Universal Connector	9/1/2000	6/6/2011
2064749	CA	Universal Connector	10/18/1994	6/6/2011
5385372	US	Luer Connector With Integral Closure	1/31/1995	1/8/2013
5772638	US	Protector For Needle	6/30/1998	9/17/2016
5433703	US	Guarded Winged Needle Assembly	7/18/1995	7/18/2012
5562636	US	Needle Protector Sheath	10/8/1996	7/15/2014
5562637	US	Needle Protector Sheath	10/8/1996	7/15/2014
2153091	CA	Needle Protector Sheath	1/29/2008	6/30/2015
5704924	US	Easy Use Needle Protector Sheath	1/6/1998	1/11/2016
5951529	US	Needle Protector Sheath	9/14/1999	7/15/2014
3809563	JP	Easy Use Needle Protector Sheath	6/2/2006	12/20/2016
717410	AU	Easy Use Needle Protector Sheath	7/6/2000	12/20/2016
6089527	US	Squeeze Clamp For Flexible Tubing	7/18/2000	10/3/2017
6113062	US	Squeeze Clamp	9/5/2000	1/28/2019
6042570	US	Needle Point Protection Sheath	3/28/2000	2/11/2019
6595965	US	Needle Protector Sheath	7/22/2003	7/15/2014
6196519	US	Squeeze Clamp For Flexible Tubing	3/6/2001	10/3/2017
6193694	US	Needle Point Protection Sheath	2/27/2001	2/11/2019
6517522	US	Tubular Intravenous Set	2/11/2003	4/3/2020
743589	AU	Needle Point Protector Sheath	5/16/2002	2/9/2020
6616635	US	Tubular Intravenous Set	9/9/2003	7/26/2020
6685680	US	Tapered Intravenous Cannula	2/3/2004	4/20/2019
7591804	US	Short-Winged Needle And Guard	9/22/2009	5/24/2027
7025744	US	Injection Site For Male Luer Or Other Tubular Connector	4/11/2006	10/4/2022
3843414	JP	Closure Needle Protector Sheath	8/25/2006	7/5/2015
6517522	US	Tubular Intravenous Set	2/11/2003	4/3/2020
6530911	US	Set With Angled Needle	3/11/2003	6/28/2020

In addition to the issued patents and pending patent applications owned by us, in the United States and selected non-U.S. markets, we possess trade secrets and proprietary know-how relating to our products. Any of our trade secrets, know-how or other technology not protected by a patent could be misappropriated, or independently developed by, a competitor and could, if independently invented and patented by a competitor, under some circumstances, be used to prevent us from further use of such information, know-how or technology.

Our strategy is to develop patent portfolios for our research and development projects. We monitor the activities of our competitors and other third parties with respect to their use of intellectual property. We intend to aggressively defend the patents we hold, and we intend to vigorously contest claims other patent holders may bring against us.

The medical device industry is characterized by the existence of a large number of patents and frequent litigation based on allegations of patent infringement. While we attempt to ensure that our products and methods do not infringe other parties' patents and proprietary rights, our competitors may assert that our products, or the methods that we employ, are covered by patents held by them. In addition, our competitors may assert that future products and methods we may market infringe their patents.

We require our employees, consultants and advisors to execute confidentiality agreements with us. We also require our employees to agree to disclose and assign to us all inventions conceived by them during their employment with us. Similar obligations are imposed upon consultants and advisors performing work for us relating to the design or manufacture of our product. Despite efforts taken to protect our intellectual property, unauthorized parties may attempt to copy aspects of our products or to obtain and use information that we regard as proprietary.

Manufacturing

The manufacture of our products is accomplished through a complementary combination of outsourcing and internal production. We have manufacturing facilities in Mexico, Germany and Italy. We outsource the manufacture of premixed dialysate, needles, some blood tubing sets, and some components.

We have single-source suppliers for a number of components as well as finished goods. In most instances, there are alternative sources of supply available. Where obtaining a second source is more difficult, we have tried to establish supply agreements that better protect our continuity of supply, although we do not have supply agreements with all of our single-source suppliers. Where we have no agreements in place, we generally work to maintain enough inventory of the single-sourced component to allow us to satisfy our requirements for the component while we secure an alternative source of supply. Our most critical single-source supply relationships are with Membrana GmbH, or Membrana, and Kawasumi Laboratories, or Kawasumi.

Membrana supplies the fibers used in the filters pre-attached to our System One cartridges. In 2007, we granted Membrana exclusive supply rights under a ten year contract scheduled to expire in 2017. We also have the right to obtain fiber from Asahi Kuraray Medical, Inc., or Asahi, pursuant to an agreement we signed with Asahi in March 2010. In the event Membrana is unable for any reason to supply fiber to us, we would try to shift to fiber supplied by Asahi, however, this would take time to accomplish and we do not presently have the regulatory approvals necessary to use Asahi fiber in our System One cartridge in the United States. There can be no assurance that any interruption in supply of fiber from Membrana would not hurt our business, at least in the near term.

We purchase the majority of our finished goods of ReadySet blood tubing sets and all of our needles from Kawasumi, headquartered in Tokyo, Japan, with manufacturing facilities in Thailand. The remainder of our blood tubing sets are manufactured at our manufacturing facility in Tijuana, Mexico. Kawasumi's contractual obligation to manufacture blood tubing sets expires in January 2012, with opportunities to extend

the term beyond that date. Under the terms of this agreement, we supply Kawasumi with molded component parts and Kawasumi in turn uses these components to manufacture finished goods blood tubing sets, which are then purchased by us. We have committed to purchase from Kawasumi a minimum quantity of blood tubing sets over the term of the agreement. We believe that this minimum purchase commitment is less than our anticipated requirements for blood tubing sets. Kawasumi's contractual obligation to supply blood tubing sets to us can be, at times, less than our forecasted demand. In the event Kawasumi supplies no more than the amount of their required maximum monthly supply, or upon any interruption in supply of blood tubing sets, we anticipate that we would be able to cover at least a significant portion of any shortfall by manufacturing additional blood tubing sets at our Mexican facility. However, there can be no assurance that any shortfall or interruption in supply of blood tubing sets from Kawasumi would not hurt our business, at least in the near term.

We also have an agreement with Kawasumi for the manufacture of needles. Virtually all of these needles rely on our patented guarded needle technology. Kawasumi's obligation to supply needles to us expires in February 2014, with opportunities to extend the term beyond that date. We have committed to purchase from Kawasumi a minimum quantity of needles over the term of the contract. We believe that this minimum purchase commitment is less than our anticipated requirements for needles. Kawasumi presently supplies all of our needle requirements, but Kawasumi's contractual obligation to supply needles to us can be, at times, less than our forecasted demand. In the event Kawasumi supplies no more than the amount of their required maximum monthly supply, we may not have enough needle supply to meet the demands of our customers. We maintain a limited extra supply of needles to mitigate against the risk of any intermittent shortfalls in supply. However, there can be no assurance that any interruption in needle supply would not impair our needle sales, at least in the near term.

We purchase bicarbonate-based premixed dialysate from B. Braun Medizintechnologie GmbH, or B. Braun, and bicarbonate-based and lactate-based premixed dialysate from Laboratorios PISA, or PISA. We have a supply agreement with B. Braun that obligates B. Braun to supply the dialysate to us for an indefinite period until either party provides twelve months notice of termination in exchange for a minimum purchase commitment, which we believe is less than our anticipated requirements. Our supply agreement with PISA extends through December 2011, with opportunities to extend the term beyond that date. We have committed to purchase from PISA a minimum quantity of premixed dialysate over the term of the agreement, which we believe is less than our anticipated requirements. With these two suppliers, we believe we have a stable supply of premixed dialysate for our customers.

Government Regulation

Food and Drug Administration

In the United States, our products are subject to regulation by the FDA, which regulates our products as medical devices. The FDA regulates the design, development, clinical testing, manufacture, labeling, distribution, import and export, sale and promotion of medical devices. Noncompliance with applicable FDA requirements can result in, among other things, fines, injunctions, civil penalties, recall or seizure of products, total or partial suspension of production, failure of the government to grant pre-market clearance or pre-market approval for devices, withdrawal of marketing clearances or approvals and criminal prosecution.

Unless an exemption applies, all medical devices must receive either prior 510(k) clearance or pre-market approval, or "PMA" approval, from the FDA before they may be commercially distributed in the United States.

The FDA classifies medical devices into one of three classes:

- Class I devices, which are subject to only general controls (e.g., labeling, medical devices reporting, and prohibitions against adulteration and misbranding) and, in some cases, to the 510(k) premarket clearance requirements;
- Class II devices, generally requiring 510(k) premarket clearance before they may be commercially marketed in the United States; and

- Class III devices, consisting of devices deemed by the FDA to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices, or devices deemed not substantially equivalent to a predicate device, generally requiring submission of a PMA supported by clinical trial data.

Submissions to obtain 510(k) clearance and pre-market approval must be accompanied by a user fee, unless exempt. In addition, the FDA can also impose restrictions on the sale, distribution or use of devices at the time of their clearance or approval, or subsequent to marketing.

FDA Regulatory Clearance Status

We currently have all of the regulatory clearances required to market the System One in the United States in both the home and critical care markets. The FDA has cleared the System One for the treatment, under a physician's prescription, of renal failure or fluid overload using hemofiltration, hemodialysis and/or ultrafiltration. The FDA has also specifically cleared the System One for home hemodialysis use under a physician's prescription.

We received our first clearance from the FDA for a predecessor model to the System One in January 2001 for hemofiltration and ultrafiltration. In July 2003, we received expanded clearance from the FDA for the System One for hemodialysis, hemofiltration and ultrafiltration. Then in June 2005, we received FDA clearance specifically allowing us to promote home hemodialysis using the System One. To date we have received a total of 26 product clearances from the FDA since our inception in December 1998 for our System One and related products. We continue to seek opportunities for product improvements and feature enhancements, which will, from time to time, require FDA clearance before market launch.

We have received a total of 24 product clearances to market Medisystems products that support the in-center market. These clearances, the first of which was received in 1981, cover blood tubing sets used for hemodialysis, needle sets used in hemodialysis and apheresis, and other components such as intravenous administration sites, Medics and transducer protectors, used primarily for hemodialysis.

FDA Clearance Procedures

510(k) Clearance Pathway. When we are required to obtain a 510(k) clearance for a device that we wish to market, we must submit a pre-market notification to the FDA demonstrating that the device is substantially equivalent to (1) a device that was legally marketed prior to May 28, 1976 and for which the FDA has not yet required premarket approval; (2) a device which has been reclassified from Class III to Class II or I; or (3) a novel device classified into Class I or II through de novo classification. If the FDA agrees that the device is substantially equivalent to the predicate, it will subject the device to the same classification and degree of regulation as the predicate device, thus effectively granting clearance to market it. The FDA attempts to respond to a 510(k) pre-market notification within 90 days of submission of the notification (or in some instances 30 days under what is referred to as "special" 510(k) submission), but the response may be a request for additional information or data, sometimes including clinical data. As a practical matter, pre-market clearance can take significantly longer, including up to one year or more.

After a device receives 510(k) clearance for a specific intended use, any modification that could significantly affect its safety or effectiveness, or that constitutes a major change in its intended use, would require a new 510(k) clearance or could require pre-market approval. In the first instance, the manufacturer may determine that a change does not require a new 510(k) clearance. The FDA can review any such decision and can disagree with a manufacturer's determination. If the FDA disagrees with a manufacturer's determination that a new clearance or approval is not required for a particular modification, the FDA can require the manufacturer to cease marketing and/or recall the modified device until 510(k) clearance or pre-market approval is obtained.

Pre-market Approval Pathway. A pre-market approval application must be submitted if the device cannot be cleared through the 510(k) process. The pre-market approval process is much more demanding than the 510(k) pre-market notification process. A pre-market approval application must be supported by extensive data and information including, but not limited to, technical, preclinical and clinical trials, manufacturing and

labeling to demonstrate to the FDA's satisfaction the safety and effectiveness of the device. After the FDA determines that a pre-market approval application is complete, the FDA accepts the application and begins an in-depth review of the submitted information. The FDA, by statute and regulation, has 180 days to review an accepted pre-market approval application, although the review generally occurs over a significantly longer period of time, and can take up to several years. During this review period, the FDA may request additional information or clarification of information already provided. Also during the review period, an advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. In addition, the FDA will conduct a pre-approval inspection of the manufacturing facility to ensure compliance with the Quality System Regulations. New pre-market approval applications or supplemental pre-market approval applications are required for modifications that affect the safety or effectiveness of the device. These types of changes include changes to the manufacturing process, labeling, use and design of the approved device. PMA supplements often require submission of the same type of information as a pre-market approval application, except that the supplement is limited to information needed to support any changes from the device covered by the original pre-market approval application, and may not require as extensive clinical data or the convening of an advisory panel.

Clinical Trials. A clinical trial is almost always required to support a pre-market approval application and is sometimes required for a 510(k) pre-market notification. Clinical trials for devices that involve significant risk, referred to as significant risk devices, require submission of an application for an IDE to the FDA. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. Clinical trials for a significant risk device may begin once the IDE application is approved by the FDA and the institutional review board, or IRB, overseeing the clinical trial. If FDA fails to respond to an IDE application within 30 days of receipt, the application is deemed approved, but IRB approval would still be required before a study could begin. Products that are not significant risk devices are deemed to be "non-significant risk devices" under FDA regulations, and are subject to abbreviated IDE requirements, including informed consent, IRB approval of the proposed clinical trial and submission of certain reports to the IRB. Clinical trials are subject to extensive recordkeeping and reporting requirements. Our clinical trials must be conducted under the oversight of an IRB at each clinical study site and in accordance with applicable regulations and policies including, but not limited to, the FDA's good clinical practice, or GCP, requirements.

Continuing FDA Regulation

After a device is placed on the market, numerous regulatory requirements apply. These include, among others:

- product listing and establishment registration, which helps facilitate FDA inspections and other regulatory action;
- Quality System Regulations, which require manufacturers to have a quality system for the design, manufacture, packaging, labeling, storage, installation, and servicing of finished medical devices;
- labeling regulations, which govern product labels and labeling, prohibit the promotion of products for unapproved, or off-label, uses and impose other restrictions on labeling and promotional activities;
- clearance of product modifications that could significantly affect safety or efficacy or that would constitute a major change in intended use of one of our cleared devices;
- medical device reporting, or MDR, regulations, which require that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur; and
- the FDA's recall authority, whereby it can ask, or under certain conditions order, device manufacturers to recall from the market a product that is in violation of governing laws and regulations;
- regulations pertaining to voluntary recalls; and
- notices of corrections or removals.

MDR Regulations. The MDR regulations require that we report to the FDA any incident in which our product may have caused or contributed to a death or serious injury, or in which our product malfunctioned and, if the malfunction were to recur, would likely cause or contribute to a death or serious injury. To date, a majority of our MDRs had been submitted to comply with the FDA's blood loss policy for routine dialysis treatments. This policy, which is no longer in effect, required manufacturers to file MDR reports related to routine dialysis treatments if the patient experiences blood loss greater than 20cc.

FDA Inspections. We have registered with the FDA as a medical device manufacturer. The FDA seeks to ensure compliance with regulatory requirements through periodic, unannounced facility inspections and these inspections may include the manufacturing facilities of our subcontractors. Failure to comply with applicable regulatory requirements can result in enforcement action by the FDA, which may include any of the following:

- warning letters or untitled letters;
- fines, injunctions, and civil penalties;
- administrative detention, which is the detention by the FDA of medical devices believed to be adulterated or misbranded;
- voluntary or mandatory recall or seizure of our products;
- customer notification, or orders for repair, replacement or refund;
- operating restrictions, partial suspension or total shutdown of production;
- refusal to review pre-market notification or pre-market approval submissions;
- rescission of a substantial equivalence order or suspension or withdrawal of a pre-market approval; and
- criminal prosecution.

The FDA has inspected our Lawrence, Massachusetts facility and quality system multiple times. In our first inspection, one observation was made, but was rectified during the inspection, requiring no further response from us. Our subsequent inspections, including our most recent inspection in 2010, resulted in no inspectional observations. Medisystems has been inspected by the FDA on multiple occasions, and all inspections resulted in no action indicated. We cannot provide assurance that we can maintain a comparable level of regulatory compliance in the future at our facilities.

Foreign Regulation of Medical Devices

Clearance or approval of our products by regulatory authorities comparable to the FDA may be necessary in foreign countries prior to marketing the product in those countries, whether or not FDA clearance has been obtained. The regulatory requirements for medical devices vary significantly from country to country. They can involve requirements for additional testing and may be time consuming and expensive. We cannot provide assurance that we will be able to obtain regulatory approvals in any other markets.

The System One cyler and related cartridges are regulated as medical devices in Canada under the Canadian Medical Device Regulations and in the EU under the Medical Device Directive. We have received four product licenses from Canada. We have obtained CE marking approval in the EU for our System One and associated ancillaries.

Our blood tubing sets, AV fistula needles, apheresis needles, dialysis priming sets, transducer protectors, Reverso, and Medic are regulated as medical devices in Canada under the Canadian Medical Device Regulations and in the EU, under the Medical Device Directive. We maintain six Medical Device Licenses in Canada under the Medisystems brandname for these products. We have received CE marking in the EU for blood tubing sets, AV fistula needles, transducer protectors, apheresis needles, Medic and its Reverso product.

Fraud and Abuse Laws

Anti-Kickback Statutes

The federal healthcare program Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the furnishing, arranging for or recommending a good or service for which payment may be made in whole or part under a federal healthcare program such as Medicare or Medicaid. The definition of remuneration has been broadly interpreted to include anything of value, including for example gifts, discounts, the furnishing of supplies or equipment, credit arrangements, payments of cash and waivers of payments. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals or otherwise generate business involving goods or services reimbursed in whole or in part under federal healthcare programs, the statute has been violated. The law contains a few statutory exceptions, including payments to bona fide employees, certain discounts and certain payments to group purchasing organizations. Violations can result in significant penalties, imprisonment and exclusion from Medicare, Medicaid and other federal healthcare programs. Exclusion of a manufacturer would preclude any federal healthcare program from paying for its products. In addition, kickback arrangements can provide the basis for an action under the Federal False Claims Act, which is discussed in more detail below.

The Anti-Kickback Statute is broad and potentially prohibits many arrangements and practices that are lawful in businesses outside of the healthcare industry. Recognizing that the Anti-Kickback Statute is broad and may technically prohibit many innocuous or beneficial arrangements, the Office of Inspector General of Health and Human Services, or OIG, issued a series of regulations, known as the safe harbors, beginning in July 1991. These safe harbors set forth provisions that, if all the applicable requirements are met, will assure healthcare providers and other parties that they will not be prosecuted under the Anti-Kickback Statute. The failure of a transaction or arrangement to fit precisely within one or more safe harbors does not necessarily mean that it is illegal or that prosecution will be pursued. However, conduct and business arrangements that do not fully satisfy each applicable safe harbor may result in increased scrutiny by government enforcement authorities such as the OIG. Arrangements that implicate the Anti-Kickback Law, and that do not fall within a safe harbor, are analyzed by the OIG on a case-by-case basis.

Government officials have focused recent enforcement efforts on, among other things, the sales and marketing activities of healthcare companies, and recently have brought cases against individuals or entities with personnel who allegedly offered unlawful inducements to potential or existing customers in an attempt to procure their business. Settlements of these cases by healthcare companies have involved significant fines and/or penalties and in some instances criminal pleas.

In addition to the Federal Anti-Kickback Statute, many states have their own anti-kickback laws. Often, these laws closely follow the language of the federal law, although they do not always have the same exceptions or safe harbors. In some states, these anti-kickback laws apply with respect to all payors, including commercial health insurance companies.

False Claims Laws

Federal false claims laws prohibit any person from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, or causing to be made, a false statement to get a false claim paid. Manufacturers can be held liable under false claims laws, even if they do not submit claims to the government, if they are found to have caused submission of false claims. The Federal Civil False Claims Act also includes whistle blower provisions that allow private citizens to bring suit against an entity or individual on behalf of the United States and to recover a portion of any monetary recovery. Many of the recent highly publicized settlements in the healthcare industry related to sales and marketing practices have been cases brought under the False Claims Act. The majority of states also have statutes or regulations similar to the federal false claims laws, which apply to items and services reimbursed under Medicaid and other state programs. Several states have false claims laws that apply regardless of the payor. Sanctions under

these federal and state laws may include civil monetary penalties, exclusion of a manufacturer's products from reimbursement under government programs, criminal fines and imprisonment.

Compliance Program

The healthcare laws and fraud and abuse laws applicable to our business are complex and subject to variable interpretations. We maintain certain compliance review, education and training and other programs to further our commitment to high standards of ethical and legal conduct and to minimize the likelihood that we would engage in conduct or enter into arrangements in violation of applicable authorities. For example, we have (i) established a compliance team consisting of representatives from our Legal, Finance, Human Resources, Regulatory Affairs/Quality Assurance and Commercial departments that meets regularly; (ii) established a compliance hotline that permits our employees to report anonymously any compliance issues that may arise; and (iii) instituted other safeguards intended to help prevent any violations of the applicable fraud and abuse laws and healthcare laws, and to remediate any situations that could give rise to violations. We also review our transactions and agreements, both past and present, to help assure they are compliant.

Through our compliance efforts, we constantly strive to structure our business operations and relationships with our customers to comply with all applicable legal requirements. However, many of the laws and regulations applicable to us are broad in scope and may be interpreted or applied by prosecutorial, regulatory or judicial authorities in ways that we cannot predict. Thus, it is possible that governmental entities or other third parties could interpret these laws differently or assert non-compliance with respect to one or more of our business operations and relationships. Moreover, the standards of business conduct expected of healthcare companies under these laws and regulations have become more stringent in recent years, even in instances where there has been no change in statutory or regulatory language. While there have been no claims asserted against us for alleged non-compliance with fraud and abuse laws or other healthcare laws, if a claim were asserted and we were not to prevail, possible penalties and sanctions could have a material effect on our financial statements or our ability to conduct our operations.

Privacy and Security

The Health Insurance Portability and Accountability Act of 1996, or HIPAA, and the rules promulgated there under require certain entities, referred to as covered entities, to comply with established standards, including standards regarding the privacy and security of protected health information (PHI) known as the HIPAA Privacy and Security Rules. Most healthcare facilities that purchase and use our products are covered entities. We are not a covered entity but due to activities that we could perform for or on behalf of covered entities, we could potentially become a business associate, as such term is defined by HIPAA. HIPAA requires that covered entities enter into agreements meeting certain regulatory requirements with their business associates which, among other things, obligate the business associates to safeguard the covered entity's PHI against improper use and disclosure. In the past, we entered into a few business associate agreements with certain of our customers that are also covered entities. Pursuant to the terms of these business associate agreements, we agreed, among other things, not to use or further disclose the covered entity's PHI except as permitted or required by the agreements or as required by law, to use reasonable safeguards to prevent prohibited disclosure of such PHI and to report to the covered entity any unauthorized uses or disclosures of such PHI. The Health Information Technology for Economic and Clinical Health Act, or HITECH made significant amendments to the HIPAA Privacy and Security Rules. Under HITECH, business associates' obligations with respect to PHI are no longer solely contractual in nature. HITECH strengthened and expanded HIPAA and made a number of HIPAA Privacy Rule requirements and a majority of HIPAA Security Rule requirements directly applicable to business associates. Accordingly, now we may be subject to HIPAA civil and criminal penalties for violation of the Privacy and Security Rule requirements. HITECH increased civil penalty amounts for violations of HIPAA and significantly strengthened enforcement by requiring the U.S. Department of Health and Human Services (HHS) to conduct periodic audits to confirm compliance and authorizing state attorneys general to bring civil actions seeking either injunctions or damages in response to violations of HIPAA that threaten the privacy of state residents. These new provisions may require us to incur

compliance related costs and may restrict our business operations. Moreover, if we fail to meet our contractual obligations under any business associate agreements, we may incur significant civil or criminal liability.

In addition, many other state and federal laws regulate the use and disclosure of health information, including state medical privacy laws and federal and state consumer protection laws. In many cases, these laws are not necessarily preempted by HIPAA, particularly if they afford greater protection to the individual than does HIPAA. These various laws may be subject to varying interpretations by courts and government agencies creating potentially complex compliance issues for our business. Other countries also have, or are developing, laws governing the collection, use and transmission of personal information and these laws could create liability for us or increase our cost of doing business.

Reimbursement

Home and In-Center Markets

Medicare regulations require that all chronic ESRD patients be under the care of a dialysis clinic, whether they are treated at home or in-clinic. We sell or rent our System One to dialysis clinics and sell our needles and blood tubing sets to dialysis clinics. These clinics are, in turn, reimbursed by Medicare, Medicaid and private insurers. According to the 2009 USRDS Annual Data Report, Medicare is the primary payor for approximately 75% of prevalent dialysis patients using hemodialysis and peritoneal dialysis. The report also indicates that approximately 15% of patients are covered by commercial insurance, with the remaining 10% of patients classified by the USRDS as "other" or "unknown." Certain centers have reported that the NxStage daily home dialysis therapy attracts a higher percentage of commercial insurance patients than other forms of dialysis.

Medicare. Medicare generally provides health insurance coverage for persons who are age 65 or older and for persons who are completely disabled. For ESRD patients, however, Medicare coverage is not dependent on age or disability. Patients are eligible for Medicare based solely on ESRD. Coverage for patients eligible for Medicare based solely on ESRD begins three months after the month in which the patient begins dialysis treatments. During this three-month waiting period either Medicaid, private insurance or the patient is responsible for payment for dialysis services. Medicare waives this waiting period for individuals who participate in a self-care dialysis training program, or are hospitalized for a kidney transplant and the surgery occurs within a specified time period.

For ESRD patients under age 65 who have any employer group health insurance coverage, regardless of the size of the employer or the individual's employment status, Medicare coverage is generally secondary to the employer coverage during the 30-month period that follows the establishment of Medicare eligibility or entitlement based on ESRD. During the period, the patient's existing insurer is responsible for paying primary benefits at the rate specified in the plan, which may be a negotiated rate or the healthcare provider's usual and customary rate. As the secondary payor during this period, Medicare will make payments up to the applicable Medicare payment rate for dialysis services to supplement any primary payments by the employer group health plan if the plan covers the services but pays only a portion of the charge for the services.

Medicare generally is the primary payor for ESRD patients after the 30-month period. Under current rules, Medicare is also the primary payor for ESRD patients during the 30-month period under certain circumstances. Medicare remains the primary payor when an individual becomes eligible for Medicare on the basis of ESRD if, (1) the individual was already age 65 or over or was eligible for Medicare based on disability and (2) the individual's private insurance coverage is not by reason of current employment or, if it is, the employer has fewer than 20 employees in the case of eligibility by reason of age, or fewer than 100 employees in the case of eligibility by reason of disability. The rules regarding entitlement to primary Medicare coverage when the patient is eligible for Medicare on the basis of both ESRD and age, or disability, have been the subject of frequent legislative and regulatory changes in recent years and there can be no assurance that these rules will not be unfavorably changed in the future.

When Medicare is the primary payor for services furnished by dialysis clinics, it reimburses dialysis clinics for 80% of the allowable rate, leaving the secondary insurance or the patient responsible for the

remaining 20%. Through 2010, providers were paid under the ESRD composite rate payment system. The Medicare composite rate was set by Congress and was intended to cover virtually all costs associated with each dialysis treatment, excluding physician services and certain separately billable drugs and laboratory services. While there was some regional variation in the Medicare composite rate, the national average for 2010 was \$155 per treatment for both independent and hospital-based dialysis facilities. This composite rate was then adjusted for patient case mix variables, potentially improving the reimbursement. For example, under the case-mix adjustment, Medicare paid more for patients with a higher body weight, and payment varies by patient age. This case-mix adjusted composite rate payment may have been beneficial to our customers, as to date, our patient population has tended to be larger and younger than the ESRD national average.

In recent years, there have been numerous initiatives on the federal and state levels for comprehensive reforms affecting the payment for, the availability of and reimbursement for healthcare services in the United States. One of these initiatives was the Medicare Improvements for Patients and Providers Act of 2008, or MIPPA, which was signed into law in 2008. As a result of this legislation, effective January 1, 2011 the Centers for Medicare and Medicaid Services, or CMS, has implemented a new prospective payment system for dialysis services that includes more items and services within the prospective payment. In November 2010, dialysis facilities were given a one-time opportunity to choose whether they wanted to transition into the prospective payment system over a four year period; or to opt out of the transition and be paid fully under the new prospective payment system beginning in January 2011. According to the Kidney Care Council, an organization representing dialysis providers, over 90% of clinics opted out of the transition and chose to be reimbursed immediately under the new system. The new prospective payment system includes a per treatment payment that incorporates the reimbursement for dialysis-related medications and laboratory tests that were previously reimbursed separately. Similar to the previous composite rate, there are also case mix, co-morbidity and other adjustors to the prospective payment. While there is some regional variation, the new rate before adjustments for patient case mix variables is \$230 per treatment for both independent and hospital-based dialysis facilities. One of the stated goals of this new prospective payment system is to encourage home dialysis, and certain elements (e.g., bundling of certain drugs into the payment, a uniform treatment payment whether dialysis is administered in the center or at home and a separate payment adjustor for home dialysis training) are intended to support this objective. However, it is not possible at this time to determine what impact this new prospective payment system will have on the adoption of home and/or daily hemodialysis or the price for which we can sell our products.

CMS rules, under the earlier composite system and the new prospective payment system, limit the number of hemodialysis treatments paid for by Medicare to three per week, unless there is medical justification provided by the dialysis facilities on information from the patient's physician. The determination of medical justification is currently made at the local Medicare contractor level on a case-by-case basis. Based upon the clinical benefits of more frequent therapy most of our patients perform treatments more than three times a week. The adoption of our System One for more frequent therapy for ESRD would likely be slowed if Medicare or their contractors are reluctant or refuse to pay for these additional treatments. A clinic's decision as to how much it is willing to spend on home daily dialysis equipment and services will be at least partly dependent on whether Medicare will reimburse additional treatments per week based on submitted claims for medical justification.

Medicaid. Medicaid programs are state-administered programs partially funded by the federal government. These programs are intended to provide coverage for certain categories of patients whose income and assets fall below state defined levels and who are otherwise uninsured. For those who are eligible, the programs serve as supplemental insurance programs for the Medicare co-insurance portion and provide certain coverage, for example, self-administered outpatient prescription medications, that is not covered by Medicare. For ESRD treatment, state regulations generally follow Medicare reimbursement levels and coverage without any co-insurance amounts, which is pertinent mostly for the three-month waiting period. Certain states, however, require beneficiaries to pay a monthly share of the cost based upon levels of income or assets.

Private Insurers. Some ESRD patients have private insurance that covers dialysis services. Healthcare providers receive reimbursement for ESRD treatments from the patient or private insurance during a waiting period of up to three months before the patient becomes eligible for Medicare. In addition, if the private payor

is an employer group health plan, it is generally required to continue to make primary payments for dialysis services during the 30-month period following eligibility or entitlement to Medicare. In general, employers may not reduce coverage or otherwise discriminate against ESRD patients by taking into account the patient's eligibility or entitlement to Medicare benefits. It is generally believed that private insurance pays significantly more for dialysis services than Medicare and these patients with private insurance are generally viewed as more profitable to dialysis service providers.

Critical Care

For Medicare patients, both acute kidney failure and fluid overload therapies provided in an in-patient hospital setting are reimbursed under a traditional Medicare severity diagnosis related group, or MS-DRG, system. Under this system, reimbursement is determined based on a patient's primary diagnosis and is intended to cover all costs of treating the patient. The presence of acute kidney failure or fluid overload increases the severity of the primary diagnosis and, accordingly, could increase the amount reimbursed. The longer hospitalization stays and higher labor needs, which are typical for patients with acute kidney failure and fluid overload, must be managed for care of these patients to be cost-effective. We believe that there is a significant incentive for hospitals to find a more cost-efficient way to treat these patients in order to improve hospital economics for these therapies.

Our Employees

As of December 31, 2010, we had approximately 1,600 employees, including full-time, part-time and seasonal or temporary employees. From time to time we also employ independent contractors to support our engineering, marketing, sales, clinical and administrative organizations. Most of our employees are involved in the manufacture of our products and are employed outside of the United States, with the significant majority employed in Mexico.

Executive Officers

The following is a list of names, ages and background of our executive officers as of December 31, 2010:

<u>Name</u>	<u>Age</u>	<u>Position</u>
Jeffrey H. Burbank	48	Chief Executive Officer
Robert S. Brown	52	Senior Vice President, Chief Financial Officer and Treasurer
Tom Shea	48	Senior Vice President, Manufacturing Operations
Winifred L. Swan	46	Senior Vice President, General Counsel and Secretary
Joseph E. Turk, Jr.	43	President, North America
Michael J. Webb	44	Senior Vice President of Quality, Regulatory and Clinical Affairs

Jeffrey H. Burbank has been our Chief Executive Officer and a director of the Company since December 1998. Prior to joining NxStage, Mr. Burbank was a founder and the CEO of Vasca, Inc., a medical device company that developed and marketed a new blood access device for dialysis patients. Mr. Burbank also served in roles of increasing responsibility in areas of manufacturing, and sales and marketing at Gambro, a leading dialysis products company. He holds a B.S. from Lehigh University.

Robert S. Brown has been our Senior Vice President, Chief Financial Officer and Treasurer since November 2006. Prior to joining NxStage, Mr. Brown held several leadership positions in Boston Scientific's financial group including Vice President, Corporate Analysis & Control from 2005 until he joined us in 2006, where he and his team were responsible for Boston Scientific's financial, compliance and operational audits and reported directly to the Audit Committee of the Board of Directors. Mr. Brown also served as Vice President, International from 1999 through 2004, where he was responsible for the financial functions of Boston Scientific's international division in over forty countries. Previous experience also includes financial

reporting and special projects at United Technologies and public accounting and consulting at Deloitte & Touche. He holds a B.B.A. degree in Accounting from the University of Toledo and an M.B.A. from the University of Michigan, and is a certified public accountant.

Tom Shea has been our Senior Vice President of Manufacturing Operations since March 2008. Prior to joining NxStage, he held several leadership positions at Jabil Incorporated, a \$12 billion Tier I contract manufacturer. Most recently, Tom served as Jabil's Global Business Unit Manager, supporting clients in the aerospace, defense and telecommunications industries. In this capacity, he developed and implemented global operations, logistics and pricing strategies for his sector. He previously served as Operations Manager at Jabil where he had full plant profit and loss responsibility for their Massachusetts facility. Mr. Shea earned his M.B.A. at the University of Massachusetts and his B.S. in Production and Operations Management at Bryant University.

Winifred L. Swan has been our Senior Vice President since January 2005 and our Vice President and General Counsel since November 2000. From July 1995 to November 2000, Ms. Swan was Senior Corporate Counsel at Boston Scientific Corporation. She holds a B.A., cum laude, in Economics and Public Policy from Duke University and a J.D., cum laude and Order of the Coif, from the University of Pennsylvania Law School.

Joseph E. Turk, Jr. has been our President of North American operations since December 2010, Senior Vice President, Commercial Operations since January 2005 and our Vice President, Sales and Marketing since May 2000. From August 1998 to May 2000, Mr. Turk was employed at Boston Scientific Corporation as Director of New Business Development. Mr. Turk holds an A.B. degree in Economics from Wabash College and an M.B.A. in Marketing and Finance from Northwestern University's Kellogg School of Management.

Michael J. Webb has been our Senior Vice President of Quality, Regulatory and Clinical Affairs since August 2007, Vice President of Disposables Operations from January 2007 through August 2007, Vice President of Quality Assurance and Regulatory Affairs from July 2002 through January 2007, and our Vice President of Operations from July 2001 through July 2002. Prior to joining NxStage, Mr. Webb was Vice President of Operations for Mosaic Technologies, a developer of gene-based diagnostic products. Other previous positions include Director of Operations for TFX Medical and Director of Disposables Manufacturing and Logistics for Haemonetics Corporation. Mr. Webb received a B.S. degree in Industrial and Management Engineering and his M.B.A. in Manufacturing Management from Rensselaer Polytechnic Institute.

Where To Find More Information

Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 are available free of charge through our website (www.nxstage.com) under the "Investor Information" caption as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission, or SEC. In addition, we intend to disclose on our website any amendments to, or waivers from, our code of business conduct and ethics that are required to be disclosed pursuant to the rules of the SEC. We are not including the information contained on our website as part of, or incorporating it by reference into, this report. You may read and copy materials that we have filed with the SEC at the SEC's public reference room located at 100 F Street, N.E., Washington, D.C. 20549. In addition, our SEC filings are available to the public on the SEC's website (www.sec.gov).

Item 1A. Risk Factors

In addition to the factors discussed in "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere in this report, the following are some of the important risk factors that could cause our actual results to differ materially from those projected in any forward-looking statements.

Risks Related to our Business

We expect to derive a significant percentage of our future revenues from the rental or sale of our System One and the related products used with the System One and a limited number of other products.

Since our inception, we have devoted a substantial amount of our efforts to the development of the System One and the related products used with the System One. We commenced marketing the System One and the related disposable products to the critical care market in February 2003. We commenced marketing the System One for chronic hemodialysis treatment in September 2004. Prior to the acquisition of the Medisystems Corporation and certain affiliated entities, or the Medisystems Acquisition, on October 1, 2007, nearly 100% of our revenues were derived from the rental or sale of our System One and the sale of related disposables. Although the Medisystems Acquisition broadened our product offerings, we expect that in 2011 and in the foreseeable future, we will continue to derive a significant percentage of our revenues from the System One, and that we will derive the remainder of our revenues from the sale of a few key disposable products acquired in the Medisystems Acquisition, including blood tubing sets and needles. To the extent that any of our primary products are not commercially successful or are withdrawn from the market for any reason, our revenues will be adversely impacted, and we do not have other significant products in development that could readily replace these revenues.

We cannot accurately predict the size of the home hemodialysis market, and it may be smaller, and may develop more slowly than we expect.

We believe our largest future product market opportunity is the home hemodialysis market. However this market is presently very small and adoption of the home hemodialysis treatment options has been limited. The most widely adopted form of dialysis therapy used in a setting other than a dialysis clinic is peritoneal dialysis. Based on the most recently available data from the United States Renal Data System, or USRDS, less than 10% of all United States patients receiving dialysis treatment for ESRD receive either peritoneal dialysis or home hemodialysis. Because the adoption of home hemodialysis has been limited to date, the number of patients and their partners who desire to, and are capable of, administering hemodialysis treatment with a system such as the System One is unknown and there is limited data upon which to make estimates. In addition, many dialysis clinics do not presently have the infrastructure in place to support home hemodialysis and most do not have the infrastructure in place to support a significant home hemodialysis patient population. Our long-term growth will depend on the number of patients who adopt home-based hemodialysis and how quickly they adopt it, which in turn is driven by the number of physicians willing to prescribe home hemodialysis and the number of dialysis clinics able or willing to establish and support home hemodialysis therapies.

Because nearly all our home hemodialysis patients are also receiving more frequent dialysis, meaning dialysis delivered five or more times a week, the market adoption of our System One for home hemodialysis is also dependent upon the penetration and market acceptance of more frequent hemodialysis. Given the increased provider supply costs associated with providing more frequent dialysis versus conventional three-times per week dialysis, market acceptance will be impacted, especially for Medicare patients, by whether dialysis clinics are able to obtain reimbursement for additional dialysis treatments provided in excess of three times a week. Presently, we understand that some of our customers are unable to obtain such additional reimbursement in all cases, and that there are increased administrative burdens associated with articulating the medical justification for treatments beyond three times per week. Both of these factors will likely negatively impact the rate and extent of any further market expansion of our System One for home hemodialysis. Expanding Medicare reimbursement over time to predictably cover more frequent therapy, with less administrative burden for our customers, may be critical to our ability to significantly expand the market penetration of the System One in the home market and to grow our revenue in the future.

New regulations particularly impacting home hemodialysis technologies can also negatively impact the rate and extent of any further market expansion of our System One for home hemodialysis. In 2008, the Centers for Medicare and Medicaid Services, or CMS released new Conditions for Coverage applicable to our customers. These Conditions for Coverage impose water testing requirements on our patients using our PureFlow SL product. These water testing requirements increase the burden of our therapy for our patients and

may impair market adoption, especially for our PureFlow SL product. To the extent additional regulations are introduced unique to the home environment, market adoption could be even further impaired.

We are in a developing market and we will need to continue to devote significant resources to developing the home market. We cannot be certain that this market will develop, how quickly it will develop or how large it will be.

Current Medicare reimbursement rates, at three times per week, limit the price at which we can market our home products, and adverse changes to reimbursement would likely negatively affect the adoption or continued sale of our home products.

Our ability to attain profitability will be driven in part by our ability to set or maintain adequate pricing for our products. As a result of legislation passed by the United States Congress more than 30 years ago, Medicare provides broad and well-established reimbursement in the United States for ESRD. With approximately 75% of United States ESRD patients covered by Medicare, the reimbursement rate is an important factor in a potential customer's decision to use the System One or our other products and limits the fee for which we can sell or rent our products. Additionally, current CMS rules limit the number of hemodialysis treatments paid for by Medicare to three times a week, unless there is medical justification provided by the dialysis facility based on information from the patient's physician for additional treatments. Most patients using the System One in the home treat themselves, with the help of a partner, up to six times per week. To the extent that Medicare contractors elect not to pay for the additional treatments, adoption of the System One would likely be impaired. The determination of medical justification must be made at the local Medicare contractor level on a case-by-case basis, based on documentation provided by our customers. If daily therapy is prescribed, a clinic's decision as to how much it is willing to spend on dialysis equipment and services will be at least partly dependent on whether Medicare will reimburse more than three treatments per week for the clinic's patients. Medicare is switching from intermediaries to Medicare administrative contractors. This change in the reviewing entity for Medicare claims could lead to a change in whether a customer receives Medicare reimbursement for additional treatments. If an adverse change to historical payment practices occurs, market adoption of our System One in the home market may be impaired. We understand that some of our customers may not be able to obtain additional reimbursement for more frequent therapy in all cases, and that there are increased administrative burdens associated with articulating the medical justification for treatments beyond three times a week. Both of these factors will likely negatively impact the rate and extent of any further market expansion of our System One for home hemodialysis. Expanding Medicare reimbursement over time to more predictably cover more frequent therapy, with less administrative burden for our customers, may be critical to our ability to significantly expand the market penetration of the System One in the home market. Additionally, any adverse changes in the rate paid by Medicare for ESRD treatments in general would likely negatively affect demand for our products in the home market and the prices we charge for them.

CMS published, on August 12, 2010, the final rule for implementation of a new prospective payment system for dialysis treatment effective January 1, 2011. Under this new ESRD prospective payment system, CMS will make a single bundled payment to the dialysis facility for each dialysis treatment that will cover all renal dialysis services and home dialysis, and will include certain drugs (including erythropoiesis stimulating agents, or ESAs, iron, and Vitamin D). It will replace the current system which pays facilities a composite rate for a defined set of items and services, while paying separately for drugs, laboratory tests, or other services that are not included in the composite rate. The prospective payment system still limits the number of hemodialysis treatments paid by Medicare to three times a week, unless there is medical justification provided by the patient's physician for additional treatments. Although a stated goal of the prospective payment system is to encourage home dialysis, and the inclusion of drugs into the prospective rate and the retention of a home patient training payment adjustment with a modest update from current levels are intended to support this goal, it is not possible at this time to determine what impact the new payment system or healthcare legislation will have on the adoption of home and/or daily hemodialysis or the price for which we can sell our products.

We have limited operating experience, a history of net losses and an accumulated deficit of \$308.4 million at December 31, 2010. We cannot guarantee if, when and the extent to which we will become profitable, or that we will be able to maintain profitability if it is achieved.

Since inception, we have incurred negative operating margins and losses every quarter. At December 31, 2010, we had an accumulated deficit of approximately \$308.4 million. We expect our operating expenses to continue to increase as we grow our business. While we have achieved positive gross margins for our products, in aggregate, since the fourth quarter of 2007, we cannot provide assurance that our gross margins will improve or, if they do improve, the rate at which they will improve. We cannot provide assurance that we will achieve profitability, when we will become profitable, the sustainability of profitability, should it occur, or the extent to which we will be profitable.

Our customers in the System One and In-Center segments are highly consolidated, with concentrated buying power.

Fresenius and DaVita own and operate the two largest chains of dialysis clinics in the United States. Collectively, these entities provide treatment to approximately 60% of United States dialysis patients; and this percentage may continue to grow with further market consolidation. DaVita, for example, recently announced its plans to acquire DSI Renal, Inc. With less than 40% of United States dialysis patients cared for by independent dialysis clinics, our market adoption, at least within the United States, would be more constrained without the presence of both DaVita and Fresenius as customers for our System One and In-Center products.

Additionally, Fresenius is not only a dialysis service provider, it is also the leading manufacturer of dialysis equipment worldwide. On February 18, 2011 we learned that Fresenius obtained clearance for its 2008K At Home hemodialysis system for use in home chronic therapy in February 2011. DaVita does not manufacture dialysis equipment, but has certain dialysis supply purchase obligations to Gambro, a dialysis equipment manufacturer, under a long-term preferred supplier agreement. Fresenius may choose to offer its dialysis patients only the dialysis equipment Fresenius manufactures, including its recently cleared home hemodialysis system. DaVita may choose to offer their dialysis patients the equipment it contractually agreed to offer in its agreement with Gambro. Fresenius and DaVita may also choose to otherwise limit access to the equipment manufactured by competitors. DaVita is our most significant customer, and we expect it to continue to be, at least for the foreseeable future. Our earlier agreement with DaVita contained certain limited exclusivity rights which restricted our ability to sell the System One in certain markets, and to Fresenius. These restrictions do not exist under our July 2010 Amended and Restated National Service Provider Agreement with DaVita, and we have a growing percentage of our home market sales to Fresenius, which is now our second largest customer in the System One segment. However, we have no assurance that our sales to DaVita or Fresenius will continue to grow, and we cannot predict what impact Fresenius' recently cleared home hemodialysis system will have on our sales to Fresenius in the home market, or our overall performance in the home market going forward. Given the significance of DaVita and Fresenius as customers in the home market, any adverse change in either's ordering or clinical practices would have a significant adverse impact on our home market revenues, especially in the near term.

DaVita is a key customer for our System One and In-Center product lines. The partial or complete loss of DaVita as a customer would materially impair our financial results, at least in the near term.

DaVita is our most significant customer. Sales through distributors to DaVita of products accounted for nearly half of In-Center segment revenues for the twelve months ended December 31, 2010, and direct sales to DaVita accounted for approximately 34% of our System One segment revenues during 2010. Further, DaVita is our largest customer in the home market, constituting over 40% of our home hemodialysis patients. Although we expect that DaVita will continue to be a significant customer in the home market, we cannot be certain that DaVita will continue to purchase and/or rent the System One or add additional System One patients in the future. Our contract for needles with DaVita, expiring in December 2013, includes certain minimum order requirements; however, these can be reduced significantly under certain circumstances. Our contract for blood tubing sets with DaVita expired in September 2009. However, in June 2009, we entered into a five year distribution agreement in the United States with Gambro, pursuant to which Gambro will

exclusively supply our blood tubing sets, including our ReadySet and the Streamline product lines to DaVita. The partial or complete loss of DaVita as a customer for any of these product lines would adversely affect our business, at least in the near term.

We entered into a \$40.0 million term loan and security agreement with Asahi in May 2009. We are obligated to pay 50% of the interest on the first day of November and May, beginning on November 1, 2009, and repay the remaining interest and principal upon maturity in May 2013. If we fail to comply with all terms under this agreement, we may go into default, which could trigger, among other things, the acceleration of all of our indebtedness there under or the sale of our assets.

In May 2009, we entered into a \$40.0 million term loan, with Asahi. The four year term loan, maturing in May 2013, bears interest at 8% annually, payable on the first day of November and May beginning on November 1, 2009, with 50% of the interest deferred to maturity. The term loan is secured by substantially all of our assets.

The term loan and security agreement includes certain affirmative covenants including timely filings and limitations on contingent debt obligations and sales of assets. The term loan and security agreement also contains customary events of default, including nonpayment, misrepresentation, breach of covenants, material adverse effects, and bankruptcy. In the event we fail to satisfy our covenants, or otherwise go into default, Asahi has a number of remedies, including sale of our assets and acceleration of all outstanding indebtedness, subject to the rights of holders of senior security interests. Certain of these remedies would likely have a material adverse effect on our business.

We entered into a two year Loan and Security Agreement, dated as of March 10, 2010, with Silicon Valley Bank, or SVB. The terms of this Agreement may restrict our current and future operations, which could affect our ability to respond to changes in our business and to manage our operations.

On March 10, 2010, we entered into an Agreement with SVB for a \$15.0 million revolving line of credit with a maturity date of April 1, 2012. The Agreement is secured by all or substantially all of our assets. In connection with this Agreement, we amended our term loan and security agreement with Asahi to provide for certain amendments, including granting to Asahi junior liens on certain of our assets for so long as the agreement with SVB remains outstanding. Upon termination of all obligations under that facility, Asahi's security will revert to a security in all assets other than cash, bank accounts, accounts receivable, field equipment and inventory. Borrowings under the Agreement bear interest at a floating rate per annum equal to two percentage points (2.00%) above the prime rate (initial prime rate of 4.00%). Pursuant to the Agreement, we have agreed to certain financial covenants relating to liquidity requirements and adjusted EBITDA, as defined in our agreement with SVB. The Agreement contains events of default customary for transactions of this type, including nonpayment, misrepresentation, breach of covenants, material adverse effect and bankruptcy.

As of the date hereof, we do not have an outstanding balance under the revolving line of credit. However, were we to draw on the line of credit, in the event we fail to satisfy our covenants, or otherwise go into default, SVB has a number of remedies, including sale of our assets and acceleration of all outstanding indebtedness. Certain of these remedies would likely have a material adverse effect on our business.

We compete against other dialysis equipment manufacturers with much greater financial resources and established products and customer relationships, which may make it difficult for us to penetrate the market and achieve significant sales of our products. Our competitors may also introduce new products or features that could impair the competitiveness of our own product portfolio.

Our System One in the critical care market competes against Gambro AB, Fresenius Medical Care AG, Baxter Healthcare, B. Braun and others. Our System One in the home market is currently the only portable system specifically indicated for use in the home market in the United States. However, on February 18, 2011 we learned that Fresenius, our second largest customer in the System One segment, with nearly all of those sales in the home market, obtained clearance for its 2008K At Home hemodialysis system for use in home chronic therapy in February 2011. Our product lines in the in-center market compete directly against products

produced by Fresenius Medical Care AG, Gambro AB, Nipro, B. Braun, Baxter Healthcare, JMS CO., LTD and others. Our competitors each market one or more FDA-cleared medical devices for the treatment of acute or chronic kidney failure. Each of these competitors offers products that have been in use for a longer time than our System One and are more widely recognized by physicians, patients and providers. These competitors have significantly more financial and human resources, more established sales, service and customer support infrastructures and spend more on product development and marketing than we do. Many of our competitors also have established relationships with the providers of dialysis therapy and, Fresenius owns and operates a chain of dialysis clinics. The product lines of most of these companies are broader than ours, enabling them to offer a broader bundle of products and have established sales forces and distribution channels that may afford them a significant competitive advantage.

The market for our products is competitive, subject to change and affected by new product introductions and other market activities of industry participants, including increased consolidation of ownership of clinics by large dialysis chains. If we are successful, our competitors are likely to develop products that offer features and functionality similar to our products, including our System One. Improvements in existing competitive products or the introduction of new competitive products may make it more difficult for us to compete for sales, particularly if those competitive products demonstrate better reliability, convenience or effectiveness or are offered at lower prices. In addition to the recent clearance of the Fresenius 2008K At Home for use in home chronic therapy, Baxter has a research and development collaboration with DEKA Research and Development Corporation and HHD, LLC, or DEKA, and has recently indicated that it received IDE approval from the FDA and hopes to commence U.S. and Canadian clinical studies of DEKA's new home hemodialysis system in 2011 and launch in international markets as early as 2011 and obtain regulatory approval for Europe in 2012. Other small companies are also working to develop products for this market. We are unable to predict when, if ever, any of these products may attain regulatory clearance and appear in the market, or how successful they may be should they be introduced, but if additional viable products are introduced to the market, it could adversely affect our sales and growth. We also are unable to predict what impact the recent clearance of a Fresenius home hemodialysis systems will have on our sales to Fresenius or our overall home market performance. Our ability to successfully market our products could also be adversely affected by pharmacological and technological advances in preventing the progression of ESRD and/or in the treatment of acute kidney failure or fluid overload. If we are unable to compete effectively against existing and future competitors and existing and future alternative treatments and pharmacological and technological advances, it will be difficult for us to penetrate the market and achieve significant sales of our products.

Our continued growth is dependent on our development and successful commercialization of new and improved products.

Our future success will depend in part on our timely development and introduction of new and improved products that address changing market requirements. To the extent that we fail to introduce new and innovative products or incremental product improvements, we may lose revenues or market share to our competitors, which may be difficult to regain. Our inability, for technological, regulatory or other reasons, to successfully develop and introduce new or improved products could reduce our growth rate or otherwise damage our business. We cannot assure you that our developments will keep pace with the marketplace or that our new or improved products will adequately meet the requirements of the marketplace.

The success and growth of our business will depend upon our ability to achieve expanded market acceptance of our System One.

In the home market, we have to convince four distinct constituencies involved in the choice of dialysis therapy, namely operators of dialysis clinics, nephrologists, dialysis nurses and patients, that the System One provides an effective alternative to other existing dialysis equipment. In the in-center market, we have to convince all of these constituencies, but to a lesser degree, patients, that our blood tubing sets and needles provide an effective alternative to other dialysis disposables. In the critical care market, we have to convince hospital purchasing groups, hospitals, nephrologists, dialysis nurses and critical care nurses that our system provides an effective alternative to other existing dialysis equipment. Each of these constituencies use different considerations in reaching their decision. Lack of acceptance by any of these constituencies will make it

difficult for us to grow our business. We may have difficulty gaining widespread or rapid acceptance of any of our products, including the System One, for a number of reasons including:

- the failure by us to demonstrate to operators of dialysis clinics, hospitals, nephrologists, dialysis nurses, patients and others that our products are equivalent or superior to existing therapy options;
- competition from products sold by companies with longer operating histories and greater financial resources, more recognizable brand names and better established distribution networks and relationships with hospitals or dialysis clinics;
- the failure by us to continue to improve product reliability and the ease of use of our products;
- limitations on the existing infrastructure in place to support home hemodialysis, including without limitation, home hemodialysis training nurses, and the willingness, cost associated with, and ability of dialysis clinics to build that infrastructure;
- the ownership and operation of some dialysis providers by companies that also manufacture and sell competitive dialysis products;
- the introduction of competing products or treatments that may be more effective, easier to use or less expensive than ours;
- regulations that impose additional burden on patients and their caregivers, such as the recently adopted Medicare conditions for coverage which impose additional water testing requirements in connection with the use of our PureFlow SL;
- the number of patients willing and able to perform therapy independently, outside of a traditional dialysis clinic, may be smaller than we estimate; and
- the availability of satisfactory reimbursement from healthcare payors, including Medicare.

If we are unable to convince additional hospitals and healthcare providers of the benefits of our products for the treatment of acute kidney failure and fluid overload, we will not be successful in increasing our market share in the critical care market.

We sell the System One in the critical care market for use in the treatment of acute kidney failure and fluid overload. Physicians currently treat most acute kidney failure patients using conventional hemodialysis systems or dialysis systems designed specifically for use in the intensive care unit, or ICU. We will need to convince hospitals and healthcare providers that using the System One is as effective as using conventional hemodialysis systems or ICU-specific dialysis systems for treating acute kidney failure and that it provides advantages over conventional systems or other ICU-specific systems because of its significantly smaller size, ease of operation and clinical flexibility. In addition, the impact of tightened credit markets on hospitals could impair the manner in which we sell products in the critical care market. Hospitals facing pressure to reduce capital spending may choose to delay capital equipment purchases or seek alternative financing options.

Our business and results of operations may be negatively impacted by general economic and financial market conditions and such conditions may increase other risks that affect our business.

Global macro economic conditions and the world's financial markets continue to experience some degree of turmoil, resulting in reductions in available credit, foreign currency fluctuations and volatility in the valuations of securities generally. In general, we believe demand for our products in the home and in-center market will not be substantially affected by the changing market conditions as regular dialysis is a life-sustaining, non-elective therapy. However, there is no assurance that future economic changes or global uncertainties would not negatively impact our business, especially the manner and pace in which we sell equipment in the System One segment or delay equipment placements. Hospitals or clinics facing pressure to reduce capital spending may choose to rent equipment rather than purchase it outright, or to enter into other less-capital intensive purchase structures with us, which may, in turn, have a negative impact on our cash flows.

The non-cash discounts we have offered to DaVita may lead to reductions in our future net revenues that will fluctuate because the amount of the discount is based upon the number of warrants earned and our stock price.

Under our July 22, 2010 agreement with DaVita, we offered DaVita the opportunity to earn pricing discounts based upon the achievement of System One home patient growth targets at June 30, 2011, 2012 and 2013. In order to preserve cash, the discount takes the form of warrants to purchase up to 5.5 million shares of our common stock that become exercisable based on the achievement of certain System One home patient growth targets (reflecting home patients who have remained on contiguous home hemodialysis therapy for at least three full months with the System One) at June 30, 2011, 2012 and 2013, and which further require DaVita to continue to grow its home patient census every six months during the term of the agreement. The discount associated with these warrants will be measured at fair value through the date of vesting using a Black-Scholes option pricing model, and is being recognized as a reduction of revenues over the same period as the related product revenues (between seven to ten years) based on the number of warrants expected to vest. The warrants are non-transferable, must be exercised in cash and have an exercise price of \$14.22 per share, which is equal to the trailing fifteen day volume weighted average price of a share of NxStage Common Stock on the NASDAQ Global Market as of the close of business on July 21, 2010, the day prior to entering into our agreement.

The reduction of revenues recorded in connection with these warrants was not significant during 2010, based on our assumptions regarding what tiered level of warrant discounts DaVita is expected to earn. However, there can be no assurance that the value of the discount, and, therefore, the amount of reduction of revenues recorded, will not be higher in the future based upon the level of warrants DaVita actually earns under the agreement, as well as the price of our stock on the date the warrants vest. Should our stock price increase above its current price, the amount of the discount would be increased.

Healthcare reform legislation could adversely affect our revenue and financial condition.

In recent years, there have been numerous initiatives on the federal and state levels for comprehensive reforms affecting the payment for, the availability of and reimbursement for healthcare services in the United States. These initiatives have ranged from proposals to fundamentally change federal and state healthcare reimbursement programs, including providing comprehensive healthcare coverage to the public under governmental funded programs, to minor modifications to existing programs.

In March 2010, the U.S. Congress adopted and President Obama signed into law comprehensive health care reform legislation through the passage of the Patient Protection and Affordable Care Act (Pub. L. No. 111-148) and the Health Care and Education Reconciliation Act of 2010 (Pub. L. No. 111-152). Among other initiatives, these bills impose a 2.3% excise tax on domestic sales of certain medical devices after December 31, 2012. This legislation also applies a productivity adjustment to the Medicare payment rates for dialysis facilities that could cause variable annual decreases in payment rates as of 2012. Outside of the excise tax, which will impact our results of operations following December 31, 2012, and the productivity adjustments, which may impact our operations when the amount of the adjustments are announced, we cannot predict the effect such legislation will have on us. If significant reforms are made to the healthcare system in the United States, or in other jurisdictions, those reforms may have a material adverse effect on our financial condition and results of operations.

As our business continues to grow, we may have difficulty managing our growth and expanding our operations successfully.

As our business continues to grow, we will need to expand our manufacturing, sales and marketing and on-going development capabilities or contract with other organizations to provide these capabilities for us. As our operations expand, we expect that we will need to manage additional relationships with various partners, suppliers, manufacturers and other organizations. Our ability to manage our operations and growth requires us to continue to improve our information technology infrastructure, operational, financial and management controls and reporting systems and procedures. Such growth could place a strain on our administrative and

operational infrastructure. We may not be able to make improvements to our management information and control systems in an efficient or timely manner and may discover deficiencies in existing systems and controls.

If we are unable to improve or maintain strong product reliability for our products, our ability to maintain or grow our business and achieve profitability could be impaired.

We have not yet achieved our long term reliability objectives for certain of our products, and as a result we continue to incur increased service and distribution costs. This, in turn, negatively impacts our gross margins and increases our working capital requirements. Additionally, product reliability issues associated with any of our product lines could lead to decreases in customer satisfaction and our ability to grow or maintain our revenues and could negatively impact our reputation. We continue to work to improve product reliability for all products, and have achieved some improvements to date. If we are unable to continue to improve product reliability, our ability to achieve our growth objectives as well as profitability could be significantly impaired.

We have a significant amount of System One field equipment, and our inability to effectively manage this asset could negatively impact our working capital requirements and future profitability.

Because our home market relies upon an equipment service swap model and, for some of our customers, an equipment rental model, our ability to manage System One equipment is important to minimizing our working capital requirements. Both factors require that we maintain a significant level of field equipment of our System One and PureFlow SL hardware. In addition, our gross margins may be negatively impacted if we have excess equipment deployed, and unused, in the field. If we are unable to successfully track, service and redeploy equipment, we could (1) incur increased costs, (2) realize increased cash requirements and/or (3) have material write-offs of equipment. This would negatively impact our working capital requirements and future profitability.

If kidney transplantation becomes a viable treatment option for more patients with ESRD, or if medical or other solutions for renal replacement become viable, the market for our products may be limited.

While kidney transplantation is the treatment of choice for most ESRD patients, it is not currently a viable treatment for most patients due to the limited number of donor kidneys, the high incidence of kidney transplant rejection and the higher surgical risk associated with older ESRD patients. According to USRDS data, in 2008, approximately 17,400 patients received kidney transplants in the United States. The development of new medications designed to reduce the incidence of kidney transplant rejection, progress in using kidneys harvested from genetically engineered animals as a source of transplants or any other advances in kidney transplantation could limit the market for our products. The development of viable medical or other solutions for renal replacement may also limit the market for our products.

We could be subject to costly and damaging product and professional liability claims and may not be able to maintain sufficient liability insurance to cover claims against us.

If any of our employees or products is found to have caused or contributed to injuries or deaths, we could be held liable for substantial damages. Claims of this nature may also adversely affect our reputation, which could damage our position in the market. While we maintain insurance, including professional liability, product and excess liability, claims may be brought against us that could result in court judgments or settlements in amounts that are in excess of the limits of our insurance coverage. In addition, due to the recent tightening of global credit and the disruption in the financial markets, there may be a disruption in our insurance coverage or delay or disruption in the payment of claims by our insurance providers. Our insurance policies also have various exclusions, and we may be subject to a product or professional liability claim for which we have no coverage. We will have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance.

Any product liability or professional liability claim brought against us, with or without merit, could result in the increase of our product liability or professional liability insurance rates, respectively, or the inability to secure additional insurance coverage in the future. A product liability claim, whether meritorious or not, could be time consuming, distracting and expensive to defend and could result in a diversion of management and financial resources away from our primary business, in which case our business may suffer.

We maintain insurance at levels deemed adequate by management; however, future claims could exceed our applicable insurance coverage.

We maintain insurance for property and general liability, directors' and officers' liability, product liability, workers compensation, and other coverage in amounts and on terms deemed adequate by management based on our expectations for future claims. Future claims could, however, exceed our applicable insurance coverage, or our coverage could not cover the applicable claims.

We face risks associated with having international manufacturing operations, and if we are unable to manage these risks effectively, our business could suffer.

We operate manufacturing facilities in Germany, Italy and Mexico. We also purchase components, products and supplies from foreign vendors. We are subject to a number of risks and challenges that specifically relate to these international operations, and we may not be successful if we are unable to meet and overcome these challenges. Significant among these risks are risks relating to foreign currency, in particular the Euro, Peso and Thai Baht. We do not currently hedge our foreign currency transactions. To the extent we fail to control our exchange rate risk, our gross margins and profitability could suffer and our ability to maintain mutually beneficial and profitable relationships with foreign vendors could be impaired. In addition to these risks, through our international operations, we are exposed to costs and challenges associated with sourcing and shipping goods internationally and importing and exporting goods, difficulty managing operations in multiple locations, local regulations that may restrict or impair our ability to conduct our operations, and health issues, such as pandemic disease risk, which could disrupt our manufacturing and logistical and import activities.

We obtain some of our raw materials, components and finished goods from a single source or a limited group of suppliers. We also obtain sterilization services from a single supplier. The partial or complete loss of one of these suppliers could cause significant production delays, an inability to meet customer demand, and a substantial loss in revenues.

We depend upon a number of single-source suppliers for some of the raw materials and components we use in our products. We also depend upon one single-source supplier for certain of our finished goods and a single-vendor for sterilization services. Our most critical single-source supply relationships are with Membrana and Kawasumi. Membrana is our sole supplier of the fiber used in our filters for System One products. Kawasumi is our only supplier of needles and certain blood tubing sets that we sell to our customers. Our dependence upon these and other single-source suppliers of raw materials, components, finished goods and sterilization services exposes us to several risks, including disruptions in supply, price increases, late deliveries, and an inability to meet customer demand. This could lead to customer dissatisfaction, damage to our reputation, or customers switching to competitive products. Any interruption in supply could be particularly damaging to our customers using the System One to treat chronic ESRD and who need access to the System One and related disposables to continue their therapy.

Finding alternative sources for these raw materials, components, finished goods and sterilization services would be difficult and in many cases entail a significant amount of time and disruption. In the case of Membrana, for fiber, we are contractually prevented from obtaining an alternative source of fiber for our System One products. Our relationship with Asahi could afford us back-up supply in the event of an inability to supply by Membrana, however, switching to Asahi fiber at this time would likely entail significant delays and difficulties. We do not have the regulatory approvals necessary to use Asahi fiber in our System One cartridge in the United States. Additionally, the performance of Asahi fiber in our System One has not yet been validated. We purchase the majority of our finished goods of ReadySet blood tubing sets and all of our

needles from Kawasumi. Kawasumi's contractual obligation to manufacture blood tubing sets expires in January 2012, with opportunities to extend the term beyond that date. Kawasumi's contractual obligation to supply needles to us expires in February 2014, with opportunities to extend the term beyond that date. Kawasumi's contractual obligation to supply needles and blood tubing sets to us can be, at times, less than our forecasted demand. In the event Kawasumi supplies no more than the amount of their required maximum monthly supply, we may not have enough needle or blood tubing set supply to meet the demands of our customers. We maintain a limited extra supply of needles to mitigate against the risk of any intermittent shortfalls in needle supply, and we have the ability to manufacture additional blood tubing sets at our manufacturing facility in Tijuana, Mexico. However, there can be no assurance that any interruption in needle or blood tubing set supply would not impair our business, at least in the near term.

Our In-Center segment relies heavily upon third-party distributors.

We sell the majority of our In-Center segment products through several distributors, which collectively accounted for substantially all of In-Center revenues during 2010, 2009 and 2008, with Henry Schein and Gambro being our most significant distributors. Our distribution agreement with Henry Schein expires in April 2012. Our distribution agreement with Gambro expires in June 2014. The loss of Gambro or Henry Schein as our distributors for any reason could materially adversely affect our business, at least in the near term.

Unless we can demonstrate sufficient product differentiation in our blood tubing set business through Streamline or products that we introduce in the future, we will continue to be susceptible to further pressures to reduce product pricing and more vulnerable to the loss of our blood tubing set business to competitors in the dialysis industry.

Our blood tubing set business has historically been a commodities business. Prior to the Medisystems Acquisition, Medisystems competed favorably and gained share through the development of a high quality, low-cost, standardized blood tubing set, which could be used on several different dialysis machines. Our products continue to compete favorably in the dialysis blood tubing set business, but are increasingly subject to pricing pressures, especially given recent market consolidation in the United States dialysis services industry, with Fresenius and DaVita collectively controlling approximately 60% of the United States dialysis services business. Unless we can successfully demonstrate to customers the differentiating features of the Streamline product or products that we introduce in the future, we may be susceptible to further pressures to reduce our product pricing and more vulnerable to the loss of our blood tubing set business to competitors in the dialysis industry.

The activities of our business involve the import of finished goods into the United States from foreign countries, subject to customs inspections and duties, and the export of components and certain other products from other countries into Germany, Mexico, Thailand and Italy. To a lesser, but increasing degree, our business also involves the export of finished goods from the United States to foreign countries. If we misinterpret or violate these laws, or if laws governing our exemption from certain duties change, we could be subject to significant fines, liabilities or other adverse consequences.

We import into the United States disposable medical supplies from Germany, Thailand and Mexico. We also import into the United States disposable medical components from Germany and Italy and export components and assemblies into Mexico, Thailand and Italy. We also import into Mexico components and assemblies from Germany, Italy and Thailand. To a lesser, but increasing degree, our business also involves the export of finished goods from the United States to foreign countries. The import and export of these items are subject to extensive laws and regulations with which we will need to comply. To the extent we fail to comply with these laws or regulations, or fail to interpret our obligations accurately, we may be subject to significant fines, liabilities and a disruption to our ability to deliver product, which could cause our combined businesses and operating results to suffer. To the extent there are modifications to the Generalised System of Preferences or cancellation of the Nairobi Protocol Classification such that our products would be subject to duties, our profitability would also be negatively impacted.

The success of our business depends on the services of each of our senior executives as well as certain key engineering, scientific, manufacturing, clinical and marketing personnel, the loss of whom could negatively affect the combined businesses.

Our success has always depended upon the skills, experience and efforts of our senior executives and other key personnel, including our research and development and manufacturing executives and managers. Much of our expertise is concentrated in relatively few employees, the loss of whom for any reason could negatively affect our business. Competition for our highly skilled employees is intense and we cannot prevent the future resignation of any employee. We maintain key person insurance for only one of our executives, Jeffrey Burbank, our Chief Executive Officer.

Risks Related to the Regulatory Environment

We are subject to significant regulation, primarily by the FDA. We cannot market or commercially distribute our products without obtaining and maintaining necessary regulatory clearances or approvals.

Our products are medical devices subject to extensive regulation in the United States, and in foreign markets we may wish to enter. To market a medical devices in the United States, approval or clearance by the FDA is required, either through the pre-market approval process or the 510(k) clearance process. We have obtained the FDA clearance necessary to sell our current products under the 510(k) clearance process. Medical devices may only be promoted and sold for the indications for which they are approved or cleared. In addition, even if the FDA has approved or cleared a product, it can take action affecting such product approvals or clearances if serious safety or other problems develop in the marketplace. We may be required to obtain 510(k) clearances or pre-market approvals for additional products, product modifications, or for new indications of our products. Regulatory pathways for such clearances may be difficult to define and could change. For example, we recently completed an approval IDE study intended to support a home nocturnal indication for the System One. Enrollment started in the first quarter of 2008 and we submitted the associated 510(k) to the FDA in 2010. We met our primary safety and efficacy endpoints for the study. Nevertheless, the FDA recently notified us that their standards for what will be required for a home nocturnal clearance may change from what was required in our approval IDE. We continue to discuss with the FDA what the pathway to clearance for our product should be, and are evaluating our next steps. Although we do not see the delay in timing for our home nocturnal clearance as material to our opportunities, we cannot be certain when this clearance will be obtained. We also cannot provide assurance that this or other clearances or approvals might be. Delays in obtaining clearances or approvals could adversely affect our ability to introduce new products or modifications to our existing products in a timely manner, which would delay or prevent commercial sales of our products. Although the 510(k) regulation has not been formally changed, the FDA has announced that it is intending to implement modifications to the 510(k) process. Any changes in regulatory policies could have an adverse affect on our ability to sell and promote our products and our business as a whole.

Modifications to our marketed devices may require new regulatory clearances or pre-market approvals, or may require us to cease marketing or recall the modified devices until clearances or approvals are obtained.

Any modifications to a 510(k) cleared device that could significantly affect its safety or effectiveness, or would constitute a major change in its intended use, requires the submission of another 510(k) pre-market notification to address the change. Although in the first instance we may determine that a change does not rise to a level of significance that would require us to make a pre-market notification submission, the FDA may disagree with us and can require us to submit a 510(k) for a significant change in the labeling, technology, performance specifications or materials or major change or modification in intended use, despite a documented rationale for not submitting a pre-market notification. We have modified various aspects of our products and have filed and received clearance from the FDA with respect to some of the changes in the design of our products. If the FDA requires us to submit a 510(k) for any modification to a previously cleared device, or in the future a device that has received 510(k) clearance, we may be required to cease marketing the device, recall it, and not resume marketing until we obtain clearance from the FDA for the modified version of the device. Also, we may be subject to regulatory fines, penalties and/or other sanctions authorized by the Federal Food, Drug, and Cosmetic Act. In the future, we intend to introduce new products and enhancements and improvements to existing products. We cannot provide assurance

that the FDA will clear any new product or product changes for marketing or what the timing of such clearances might be. In addition, new products or significantly modified marketed products could be found to be not substantially equivalent and classified as products requiring the FDA's approval of a pre-market approval application, or PMA, before commercial distribution would be permissible. PMAs usually require substantially more data than 510(k) submissions and their review and approval or denial typically takes significantly longer than a 510(k) decision of substantial equivalence. Also, PMA products require approval supplements for any change that affects safety and effectiveness before the modified device may be marketed. Delays in our receipt of regulatory clearance or approval will cause delays in our ability to sell our products, which will have a negative effect on our revenues growth.

Even if we obtain the necessary FDA clearances or approvals, if we or our suppliers fail to comply with ongoing regulatory requirements our products could be subject to restrictions or withdrawal from the market.

We are subject to the Medical Device Reporting, or MDR, regulations that require us to report to the FDA if our products may have caused or contributed to patient death or serious injury, or if our device malfunctions and a recurrence of the malfunction would likely result in a death or serious injury. We must also file reports of device corrections and removals and adhere to the FDA's rules on labeling and promotion. Our failure to comply with these or other applicable regulatory requirements could result in enforcement action by the FDA, which may include any of the following:

- untitled letters, warning letters, fines, injunctions and civil penalties;
- administrative detention, which is the detention by the FDA of medical devices believed to be adulterated or misbranded;
- customer notification, or orders for repair, replacement or refund;
- voluntary or mandatory recall or seizure of our products;
- operating restrictions, partial suspension or total shutdown of production;
- refusal to review pre-market notification or pre-market approval submissions;
- rescission of a substantial equivalence order or suspension or withdrawal of a pre-market approval; and
- criminal prosecution.

Our products are subject to market withdrawals or product recalls after receiving FDA clearance or approval, and market withdrawals and product recalls could cause the price of our stock to decline and expose us to product liability or other claims or could otherwise harm our reputation and financial results.

Medical devices can experience performance problems in the field that require review and possible corrective action by us or the product manufacturer. We cannot provide assurance that component failures, manufacturing errors, design defects and/or labeling inadequacies, which could result in an unsafe condition or injury to the operator or the patient will not occur. These could lead to a government mandated or voluntary recall by us. The FDA has the authority to require the recall of our products in the event a product presents a reasonable probability that it would cause serious adverse health consequences or death. Similar regulatory agencies in other countries have similar authority to recall devices because of material deficiencies or defects in design or manufacture that could endanger health. We believe that the FDA would request that we initiate a voluntary recall if a product was defective or presented a risk of injury or gross deception. Any recall would divert management attention and financial resources, could cause the price of our stock to decline and expose us to product liability or other claims and harm our reputation with customers.

If we or our contract manufacturers fail to comply with FDA's Quality System Regulations, our manufacturing operations could be interrupted, and our product sales and operating results could suffer.

Our finished goods manufacturing processes, and those of some of our contract manufacturers, are required to comply with the FDA's Quality System Regulations, or QSRs, which cover the procedures and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization,

storage and shipping of our devices. The FDA enforces its QSRs through periodic unannounced inspections of manufacturing facilities. We and our contract manufacturers have been, and anticipate in the future being, subject to such inspections. We were inspected by the FDA in the second quarter of 2010, and received no inspectional observations. While all of our previous inspections have resulted in no significant observations, we cannot provide assurance that we can maintain a comparable level of regulatory compliance in the future at our facilities, or that future inspections would have the same result.

If one of our manufacturing facilities or those of any of our contract manufacturers fails to take satisfactory corrective action in response to an adverse QSR inspection, the FDA could take enforcement action, including issuing a public warning letter, shutting down our manufacturing operations, embargoing the import of components from outside of the United States, recalling our products, refusing to approve new marketing applications, instituting legal proceedings to detain or seize products or imposing civil or criminal penalties or other sanctions, any of which could cause our business and operating results to suffer.

We may be subject to fines, penalties or injunctions if we are determined to be promoting the use of our products in a manner not consistent with our products' cleared indications for use or with other state or federal laws governing the promotion of our products.

Our promotional materials and other product labeling must comply with FDA and other applicable laws and regulations. If the FDA determines that our promotional materials or other product labeling constitute promotion of an unapproved, or uncleared use, it could request that we modify our materials or subject us to regulatory or enforcement actions, including the issuance of an untitled letter, a warning letter, injunction, seizure, civil fine and criminal penalties. Other regulatory agencies, federal, state and foreign, including the U.S. Federal Trade Commission, have issued guidelines and regulations that govern how we promote our product, including how we use endorsements and testimonials. If our promotional materials are inconsistent with these guidelines or regulations, we could be subject to enforcement actions, which could result in significant fines, costs and penalties. Our reputation could also be damaged and the adoption of our products could be impaired.

Failure to obtain regulatory approval in foreign jurisdictions would prevent us from marketing our products outside the United States.

Historically, we have not sold or marketed the System One outside the United States and Canada. In 2009, we began entering into arrangements with distributors to sell the System One and certain of our other products outside of the United States. We are currently selling the System One in Europe and the Middle East, and are assessing other international markets for the System One as well. Our In-Center products are presently sold in the United States as well as in several other countries, through distributors. We presently have CE marking as well as Canadian regulatory authority to sell our System One as well as certain other products in Canada and Europe. However, in order to market directly our products in other foreign jurisdictions, we must obtain separate regulatory approvals and comply with numerous and varying regulatory requirements. The approval procedure varies from country to country and can involve additional testing. The time required to obtain approval abroad may be longer than the time required to obtain FDA clearance. The foreign regulatory approval process includes many of the risks associated with obtaining FDA clearance and we may not obtain foreign regulatory approvals on a timely basis, if at all. FDA clearance does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries. We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in any market outside the United States, which could negatively affect our overall market penetration. Additionally, any loss of foreign regulatory approvals, for any reason, could negatively affect our business.

We have obligations under our contracts with dialysis clinics and hospitals to protect the privacy of patient health information.

In the course of performing our business we obtain, from time to time, confidential patient health information. For example, we learn patient names and addresses when we ship our System One supplies to

home hemodialysis patients. We may learn patient names and be exposed to confidential patient health information when we provide training on our products to our customer's staff. Our home hemodialysis patients may also call our customer service representatives directly and, during the call, disclose confidential patient health information. United States federal and state laws protect the confidentiality of certain patient health information, in particular individually identifiable information, and restrict the use and disclosure of that information. At the federal level, the Department of Health and Human Services promulgated health information and privacy and security rules under the Health Insurance Portability and Accountability Act of 1996, or HIPAA. At this time, we are not a HIPAA covered entity. However, we have entered into business associate agreements with covered entities that contain commitments to protect the privacy and security of patients' health information and, in some instances, require that we indemnify the covered entity for any claim, liability, damage, cost or expense arising out of or in connection with a breach of the agreement by us. If we were to violate one of these agreements, we could lose customers and be exposed to liability and/or our reputation and business could be harmed. In addition, the Health Information Technology for Economic and Clinical Health Act (HITECH), enacted in February 2009, expands the HIPAA privacy and security rules, including imposing many of the requirements of those rules directly on business associates and making business associates directly subject to HIPAA civil and criminal enforcement provisions and associated penalties. Many of these requirements went into effect on February 17, 2010. We may be required to make costly system modifications to comply with the HIPAA privacy and security requirements. Our failure to comply may result in criminal and civil liability.

Many other federal and state laws apply to the use and disclosure of health information, as well as certain financial information, which could affect the manner in which we conduct our business. Such laws are not necessarily preempted by HIPAA, in particular those laws that afford greater protection to the individual than does HIPAA or cover different subject matter. Such state laws typically have their own penalty provisions, which could be applied in the event of an unlawful action affecting health information.

We are subject to federal and state laws prohibiting "kickbacks" and false and fraudulent claims which, if violated, could subject us to substantial penalties. Additionally, any challenges to or investigation into our practices under these laws could cause adverse publicity and be costly to respond to, and thus could harm our business.

The Medicare/Medicaid anti-kickback laws, and similar state laws, prohibit payments that are intended to induce health care professionals or others either to refer patients or to acquire or arrange for or recommend the acquisition of healthcare products or services. A number of states have enacted laws that require pharmaceutical and medical device companies to monitor and report payments, gifts and other remuneration made to physicians and other health care professionals and health care organizations. In addition, some state statutes, most notably laws in Massachusetts, Minnesota, and Vermont, impose outright bans on certain gifts to physicians. Some of these laws referred to as "aggregate spend" laws or "gift" laws, carry substantial fines if they are violated. Recently, the federal Physician Payments Sunshine Act was enacted by Congress in 2010 as part of the comprehensive health care reform legislation, and it will require us to begin publicly disclosing certain payments and other transfers of value to physicians and teaching hospitals beginning in 2013. These laws affect our sales, marketing and other promotional activities by limiting the kinds of financial arrangements, including sales programs, we may have with hospitals, physicians or other potential purchasers or users of medical devices. They also impose additional administrative and compliance burdens on us. In particular, these laws influence, among other things, how we structure our sales and rental offerings, including discount practices, customer support, education and training programs and physician consulting and other service arrangements. Although we seek to structure such arrangements in compliance with all applicable requirements, these laws are broadly written, and it is often difficult to determine precisely how these laws will be applied in specific circumstances. If we were to offer or pay inappropriate inducements to purchase our products, we could be subject to a claim under the Medicare/Medicaid anti-kickback laws or similar state laws. If we fail to comply with particular reporting requirements, we could be subject to penalties under applicable federal or state laws.

Other federal and state laws generally prohibit individuals or entities from knowingly presenting, or causing to be presented, claims for payments to Medicare, Medicaid or other third-party payors that are false or fraudulent, or for items or services that were not provided as claimed. Although we do not submit claims directly to payors, manufacturers can be held liable under these laws if they are deemed to "cause" the submission of false or fraudulent claims by providing inaccurate billing or coding information to customers, by providing improper financial inducements, or through certain other activities. In providing billing and coding information to customers, we make every effort to ensure that the billing and coding information furnished is accurate and that treating physicians understand that they are responsible for all billing and prescribing decisions, including the decision as to whether to order dialysis services more frequently than three times per week. Nevertheless, we cannot provide assurance that the government will regard any billing errors that may be made as inadvertent or that the government will not examine our role in providing information to our customers concerning the benefits of daily therapy. Likewise, our financial relationships with customers, physicians, or others in a position to influence the purchase or use of our products may be subject to government scrutiny or be alleged or found to violate applicable fraud and abuse laws. False claims laws prescribe civil, criminal and administrative penalties for noncompliance, which can be substantial. Moreover, an unsuccessful challenge or investigation into our practices could cause adverse publicity, and be costly to respond to, and thus could harm our business and results of operations.

Foreign governments tend to impose strict price controls, which may adversely affect our future profitability.

Presently, our marketing efforts have been confined nearly exclusively to the United States. We have had limited activities in Canada with our System One, and in certain other jurisdictions with our In-Center products sold through distributors. In 2009, we began entering into arrangements with distributors to sell the System One and certain of our other products in Europe and the Middle East. We may, in the future, seek to market our products in other markets. In some foreign countries, particularly in the European Union, the pricing of medical devices is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to supply data that compares the cost-effectiveness of our products to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, it may not be profitable to sell our products outside of the United States, which would negatively affect the long-term growth of our business. Further, reimbursement provided to our products in other jurisdictions could change, positively or negatively. In the event reimbursements were to be negatively changed, such as, for example, in the United Kingdom, our ability to sell our products could be impaired.

Failure to comply with the United States Foreign Corrupt Practices Act could subject us to penalties and other adverse consequences.

We are subject to the United States Foreign Corrupt Practices Act which generally prohibits United States companies from engaging in bribery or other prohibited payments to foreign officials for the purpose of obtaining or retaining business and requires companies to maintain accurate books and records and internal controls, including at foreign controlled subsidiaries. While we have policies and procedures in place designed to prevent noncompliance, we can make no assurance that our employees or other agents will not engage in prohibited conduct under the Foreign Corrupt Practices Act for which we might be held responsible. If our employees or other agents are found to have engaged in such practices, we could suffer severe penalties and other consequences that may have a material adverse effect on our business, financial condition and results of operations.

Our business activities involve the use of hazardous materials, which require compliance with environmental and occupational safety laws regulating the use of such materials. If we violate these laws, we could be subject to significant fines, liabilities or other adverse consequences.

Our research and development programs as well as our manufacturing operations involve the controlled use of hazardous materials. Accordingly, we are subject to federal, state and local laws governing the use, handling and disposal of these materials. Although we believe that our safety procedures for handling and disposing of these materials comply in all material respects with the standards prescribed by state and federal regulations, we cannot completely eliminate the risk of accidental contamination or injury from these materials. In the event of an accident or failure to comply with environmental laws, we could be held liable for resulting damages, and any such liability could exceed our insurance coverage.

Risks Related to Operations

Resin is a key input material to the manufacture of our products and System One cartridge. Oil prices affect both the pricing and availability of this material. Escalation of oil prices could affect our ability to obtain sufficient supply of resin at the prices we need to manufacture our products at current rates of profitability.

We currently source resin from a small number of suppliers. Rising oil prices over the last several years have resulted in significant price increases for this material. We cannot guarantee that prices will not continue to increase. Our contracts with customers restrict our ability to immediately pass on these price increases, and we cannot guarantee that future pricing to customers will be sufficient to accommodate increasing input costs.

Distribution costs represent a significant percentage of our overall costs, and these costs are dependent upon fuel prices. Increases in fuel prices could lead to increases in our distribution costs, which, in turn, could impair our ability to achieve profitability.

We currently incur significant inbound and outbound distribution costs. Our distribution costs are dependent upon fuel prices. Increases in fuel prices could lead to increases in our distribution costs, which could impair our ability to achieve profitability.

We have labor agreements with our production employees in Italy and in Mexico. We cannot guarantee that we will not in the future face strikes, work stoppages, work slowdowns, grievances, complaints, claims of unfair labor practices, other collective bargaining disputes or in Italy, anti-union behavior, that may cause production delays and negatively impact our ability to deliver our products on a timely basis.

Our wholly-owned subsidiary in Italy has a national labor contract with Contratto collettivo nazionale di lavoro per gli addetti all'industria della gomma cavi elettrici ed affini e all'industria delle materie plastiche, and our wholly-owned subsidiary in Mexico has entered into a collective bargaining agreement with a Union named Mexico Moderno de Trabajadores de la Baja California C.R.O.C. We have not to date experienced strikes, work stoppages, work slowdowns, grievances, complaints, claims of unfair labor practices, other collective bargaining disputes, or in Italy, anti-union behavior, however we cannot guarantee that we will not be subject to such activity in the future. Any such activity would likely cause production delays, and negatively affect our ability to deliver our production commitments to customers, which could adversely affect our reputation and cause our combined businesses and operating results to suffer. Additionally, some of our key single source suppliers have labor agreements. We cannot guarantee that we will not have future disruptions, which could adversely affect our reputation and cause our business and operating results to suffer.

We do not have long-term supply contracts with many of our third-party suppliers.

We purchase raw materials and components from third-party suppliers, including some single source suppliers, through purchase orders and do not have long-term supply contracts with many of these third-party suppliers. Many of our third-party suppliers are not obligated to perform services or supply products for any specific period, in any specific quantity or at any specific price, except as may be provided in a particular purchase order. We do not maintain large volumes of inventory from most of our suppliers. If we inaccurately

forecast demand for finished goods, our ability to meet customer demand could be delayed and our competitive position and reputation could be harmed. In addition, if we fail to effectively manage our relationships with these suppliers, we may be required to change suppliers, which would be time consuming and disruptive and could lead to disruptions in product supply, which could permanently impair our customer base and reputation.

Certain of our products are recently developed and we have recently transitioned the manufacturing of certain of these products to new locations. We, and certain of our third-party manufacturers, have limited manufacturing experience with these products.

We continue to develop new products and make improvements to existing products. As such, we and certain of our third-party manufacturers have limited manufacturing experience with certain of our products. We are more exposed to risks relating to product quality and reliability until the manufacturing processes for these new products mature.

Risks Related to Intellectual Property

If we are unable to protect our intellectual property and prevent its use by third parties, we will lose a significant competitive advantage.

We rely on patent protection, as well as a combination of copyright, trade secret and trademark laws to protect our proprietary technology and prevent others from duplicating our products. However, these means may afford only limited protection and may not:

- prevent our competitors from duplicating our products;
- prevent our competitors from gaining access to our proprietary information and technology; or
- permit us to gain or maintain a competitive advantage.

Any of our patents, including those we may license, may be challenged, invalidated, circumvented or rendered unenforceable. We cannot provide assurance that we will be successful should one or more of our patents be challenged for any reason. If our patent claims are rendered invalid or unenforceable, or narrowed in scope, the patent coverage afforded our products could be impaired, which could make our products less competitive.

We cannot specify which, if any, of our patents individually or as a group will permit us to gain or maintain a competitive advantage. We cannot provide assurance that any pending or future patent applications we hold will result in an issued patent or that if patents are issued to us, that such patents will provide meaningful protection against competitors or against competitive technologies. The issuance of a patent is not conclusive as to its validity or enforceability. The United States federal courts or equivalent national courts or patent offices elsewhere may invalidate our patents or find them unenforceable. Competitors may also be able to design around our patents. Our patents and patent applications cover particular aspects of our products. Other parties may develop and obtain patent protection for more effective technologies, designs or methods for treating kidney failure. If these developments were to occur, it would likely have an adverse effect on our sales.

The laws of foreign countries may not protect our intellectual property rights effectively or to the same extent as the laws of the United States. If our intellectual property rights are not adequately protected, we may not be able to commercialize our technologies, products or services and our competitors could commercialize similar technologies, which could result in a decrease in our revenues and market share.

Our products could infringe the intellectual property rights of others, which may lead to litigation that could itself be costly, could result in the payment of substantial damages or royalties, and/or prevent us from using technology that is essential to our products.

The medical device industry in general has been characterized by extensive litigation and administrative proceedings regarding patent infringement and intellectual property rights. Products to provide kidney replacement therapy have been available in the market for more than 30 years and our competitors hold a

significant number of patents relating to kidney replacement devices, therapies, products and supplies. Although no third party has threatened or alleged that our products or methods infringe their patents or other intellectual property rights, we cannot provide assurance that our products or methods do not infringe the patents or other intellectual property rights of third parties. If our business is successful, the possibility may increase that others will assert infringement claims against us.

Infringement and other intellectual property claims and proceedings brought against us, whether successful or not, could result in substantial costs and harm to our reputation. Such claims and proceedings can also distract and divert management and key personnel from other tasks important to the success of the business. In addition, intellectual property litigation or claims could force us to do one or more of the following:

- cease selling or using any of our products that incorporate the asserted intellectual property, which would adversely affect our revenues;
- pay substantial damages for past use of the asserted intellectual property;
- obtain a license from the holder of the asserted intellectual property, which license may not be available on reasonable terms, if at all and which could reduce profitability; and
- redesign or rename, in the case of trademark claims, our products to avoid infringing the intellectual property rights of third parties, which may not be possible and could be costly and time-consuming if it is possible to do so.

Confidentiality agreements with employees and others may not adequately prevent disclosure of trade secrets and other proprietary information.

In order to protect our proprietary technology and processes, we also rely in part on confidentiality agreements with our corporate partners, employees, consultants, outside scientific collaborators and sponsored researchers, advisors and others. These agreements may not effectively prevent disclosure of confidential information and trade secrets and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover or reverse engineer trade secrets and proprietary information, and in such cases we could not assert any trade secret rights against such party. Costly and time consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect our competitive position.

We may be subject to damages resulting from claims that our employees or we have wrongfully used or disclosed alleged trade secrets of other companies.

Many of our employees were previously employed at other medical device companies focused on the development of dialysis products, including our competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. If we fail in defending such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. Even if we are successful in defending against these claims, litigation could result in substantial costs, damage to our reputation and be a distraction to management.

Risks Related to our Common Stock

Our stock price is likely to be volatile, and the market price of our common stock may drop.

The market price of our common stock could be subject to significant fluctuations. Market prices for securities of early stage companies have historically been particularly volatile. As a result of this volatility, you may not be able to sell your common stock at or above the price you paid for the stock. Some of the factors that may cause the market price of our common stock to fluctuate include:

- timing of market launch and/or market acceptance of our products;
- timing of achieving profitability from operations;

- changes in estimates of our financial results or recommendations by securities analysts or the failure to meet or exceed securities analysts' expectations;
- actual or anticipated variations in our quarterly operating results;
- future debt or equity financings;
- developments or disputes with key vendors or customers, or adverse changes to the purchasing patterns of key customers;
- disruptions in product supply for any reason, including product recalls, our failure to appropriately forecast supply or demand, difficulties in moving products across the border, or the failure of third party suppliers to produce needed products or components;
- reports by officials or health or medical authorities, the general media or the FDA regarding the potential benefits of the System One or of similar dialysis products distributed by other companies or of daily or home dialysis;
- announcements by the FDA of non-clearance or non-approval of our products, or delays in the FDA or other foreign regulatory agency review process;
- product recalls;
- defaults under our material contracts, including without limitation our credit agreement;
- regulatory developments in the United States and foreign countries;
- changes in third-party healthcare reimbursements, particularly a decline in the level of Medicare reimbursement for dialysis treatments, or the willingness of Medicare contractors to pay for more than three treatments a week where medically justified;
- litigation involving our company or our general industry or both;
- announcements of technical innovations or new products by us or our competitors;
- developments or disputes concerning our patents or other proprietary rights;
- our ability to manufacture and supply our products to commercial standards;
- significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors;
- departures of key personnel; and
- investors' general perception of our company, our products, the economy and general market conditions.

The stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations may adversely affect the trading price of our common stock. In the past, following periods of volatility in the market price of a company's securities, stockholders have often instituted class action securities litigation against those companies. Such litigation, if instituted, could result in substantial costs and diversion of management attention and resources, which could significantly harm our profitability and reputation.

Anti-takeover provisions in our restated certificate of incorporation and amended and restated bylaws and under Delaware law could make an acquisition of us more difficult and may prevent attempts by our stockholders to replace or remove our current management.

Provisions in our restated certificate of incorporation and our amended and restated bylaws may delay or prevent an acquisition of us. In addition, these provisions may frustrate or prevent attempts by our stockholders to replace or remove members of our board of directors. Because our board of directors is responsible for

appointing the members of our management team, these provisions could in turn affect any attempt by our stockholders to replace current members of our management team. These provisions include:

- a prohibition on actions by our stockholders by written consent;
- the ability of our board of directors to issue preferred stock without stockholder approval, which could be used to institute a "poison pill" that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board of directors;
- advance notice requirements for nominations of directors or stockholder proposals; and
- the requirement that board vacancies be filled by a majority of our directors then in office.

In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns in excess of 15% of our outstanding voting stock from merging or combining with us for a period of three years after the date of the transaction in which the person acquired in excess of 15% of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. These provisions would apply even if the offer may be considered beneficial by some stockholders.

If there are substantial sales of our common stock in the market by our large existing stockholders, our stock price could decline.

If our existing stockholders sell a large number of shares of our common stock or the public market perceives that existing stockholders might sell a large number of shares of common stock, the market price of our common stock could decline significantly. We have 53,718,213 shares of common stock outstanding as of December 31, 2010. Except where sales are made pursuant to an effective registration statement, shares held by our affiliates may only be sold in compliance with the volume limitations of Rule 144. These volume limitations restrict the number of shares that may be sold by an affiliate in any three-month period to the greater of 1% of the number of shares then outstanding, which approximates 537,182 shares, or the average weekly trading volume of our common stock during the four calendar weeks preceding the filing of a notice on Form 144 with respect to the sale. With the higher trading volumes we have recently observed in our stock, the number of shares that can be sold by our affiliates pursuant to Rule 144 is significantly above the 1% of shares outstanding limitation of Rule 144 as of the time of the filing of this report.

At December 31, 2010, subject to certain conditions, holders of an aggregate of approximately 9 million shares of our common stock have rights with respect to the registration of these shares of common stock with the Securities and Exchange Commission, or SEC. If we register their shares of common stock, they can more easily sell those shares in the public market.

As of December 31, 2010, 6,874,978 shares of common stock are authorized for issuance under our stock incentive plan, employee stock purchase plan and outstanding stock options. As of December 31, 2010, 6,222,962 shares were subject to outstanding options, of which 3,709,004 were exercisable and can be freely sold in the public market upon issuance, subject to the restrictions imposed on our affiliates under Rule 144.

We have filed a resale registration statement covering both shares of our common stock that we sold in a May 2008 private placement and shares of our common stock issuable upon the exercise of a warrant held by DaVita. If the holders of these shares or shares issued pursuant to the terms of the warrant are unable to sell these shares under the respective registration statements, we may be obligated to pay them damages, which could harm our financial condition. Further, these resale registration statements could result in downward pressure on the price of our common stock and may affect the ability of our stockholders to realize the current trading price of our common stock.

In 2008, we sold an aggregate of 9,555,556 shares of our common stock and warrants to purchase an additional 1,911,111 shares of our common stock in a private placement. We were required to register the common stock and the common stock issuable upon exercise of the warrants with the Securities and Exchange Commission, which we did on August 8, 2008. If the holders of the shares or the accompanying warrant shares are unable to sell such shares or warrant shares under the registration statement for more than 30 days

in any 365 day period after the effectiveness of the registration statement, we may be obligated to pay damages equal to up to 1% of the share purchase price per month that the registration statement is not effective and the investors are unable to sell their shares.

On July 22, 2010, we issued to DaVita a warrant which, subject to the achievement of certain System One growth targets, may be exercisable for up to a cumulative total of 5,500,000 shares of our common stock. In connection with issuance of this warrant we entered into a registration rights agreement with DaVita, pursuant to which (subject to certain conditions) we have agreed to file, on or prior to April 1, 2011, a registration statement on Form S-3 with respect to the resale by DaVita of any shares of our common stock issued to DaVita under the warrant. We registered the shares of common stock issuable upon the exercise of the warrant on February 16, 2011 on our automatic shelf registration statement on Form S-3 (No. 333-170654) filed on November 17, 2010.

Investors should be aware that the current or future market price of their shares of our common stock could be negatively impacted by the sale or perceived sale of all or a significant number of these shares that are available for sale pursuant to these registration statements or that will be available for sale in the future.

Our outstanding warrants, and the provisions of our Term Loan with Asahi, may result in substantial dilution to our stockholders.

Warrants held by DaVita and certain investors in our 2008 private placement could result in the issuance of up to 7,052,155 additional shares of common stock. In addition, in the event our Term Loan with Asahi reaches maturity, Asahi may require that all of the principal and interest on the Term Loan that is unpaid as of the maturity date be converted into shares of our common stock, with the number of shares to be determined based upon the average closing stock price of our common stock during the thirty business days preceding the maturity date. The issuance and sale of any of these shares could result in substantial dilution to our stockholders in the form of immediate and substantial dilution in net tangible book value per share.

Our executive officers, directors and current and principal stockholders own a large percentage of our voting common stock and could limit new stockholders' influence on corporate decisions or could delay or prevent a change in corporate control.

Our directors, executive officers and current holders of more than 5% of our outstanding common stock, together with their affiliates and related persons, beneficially hold, in the aggregate, approximately 35% of our outstanding common stock. David S. Utterberg holds approximately 10% and Credit Suisse holds approximately 6% of our outstanding common stock. Although these numbers are lower than they have been historically, due to certain recent selling by larger affiliated stockholders, these stockholders, if acting together, may nevertheless still have the ability to determine the outcome of matters submitted to our stockholders for approval, including the election and removal of directors and any merger, consolidation or sale of all or substantially all of our assets and other extraordinary transactions. The interests of this group of stockholders may not always coincide with our corporate interests or the interests of other stockholders, and they may act in a manner with which you may not agree or that may not be in the best interests of other stockholders. This concentration of ownership may have the effect of:

- delaying, deferring or preventing a change in control of our company;
- entrenching our management and/or Board;
- impeding a merger, consolidation, takeover or other business combination involving our company; or
- discouraging a potential acquirer from making a tender offer or otherwise attempting to obtain control of our company.

We may grow through additional acquisitions, which could dilute our existing shareholders and could involve substantial integration risks.

As part of our business strategy, we may acquire other businesses and/or technologies in the future. We may issue equity securities as consideration for future acquisitions that would dilute our existing stockholders, perhaps significantly depending on the terms of the acquisition. We may also incur additional debt in

connection with future acquisitions, which, if available at all, may place additional restrictions on our ability to operate our business. Acquisitions may involve a number of risks, including:

- difficulty in transitioning and integrating the operations and personnel of the acquired businesses, including different and complex accounting and financial reporting systems;
- potential disruption of our ongoing business and distraction of management;
- potential difficulty in successfully implementing, upgrading and deploying in a timely and effective manner new operational information systems and upgrades of our finance, accounting and product distribution systems;
- difficulty in incorporating acquired technology and rights into our products and technology;
- unanticipated expenses and delays in completing acquired development projects and technology integration;
- management of geographically remote units both in the United States and internationally;
- impairment of relationships with partners and customers;
- customers delaying purchases of our products pending resolution of product integration between our existing and our newly acquired products;
- entering markets or types of businesses in which we have limited experience;
- potential loss of key employees of the acquired company; and
- inaccurate assumptions of the acquired company's product quality and/or product reliability.

As a result of these and other risks, we may not realize anticipated benefits from our acquisitions. Any failure to achieve these benefits or failure to successfully integrate acquired businesses and technologies could seriously harm our business.

Item 1B. *Unresolved Staff Comments*

Not Applicable.

Item 2. *Properties*

We are headquartered in Lawrence, Massachusetts, where we lease approximately 52,000 square feet under a lease expiring in 2012 used for research and development, general and administrative support functions, customer service and IT support services. We have manufacturing facilities consisting of an 118,000 square foot facility in Tijuana, Mexico with a lease expiring in October 2011 and a 36,300 square foot facility in Modena, Italy with a lease expiring in 2012. These facilities support both our In-Center and System One Segments. We also have a 35,000 square foot facility through our relationship with Entrada with a lease expiring in 2012 where our System One equipment is serviced and repaired, and a 12,369 square foot facility in Rosdorf, Germany with a term expiring in December 2011, where our filters for the System One segment are manufactured. We believe that our existing facilities are adequate for our current needs and that suitable additional or alternative space will be available at such time as it becomes needed on commercially reasonable terms.

Item 3. *Legal Proceedings*

From time to time we may be a party to various legal proceedings arising in the ordinary course of our business. We are not currently subject to any material legal proceedings.

Item 4. [Removed and Reserved]

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters, and Issuer Purchases of Equity Securities

Market Information

Our common stock has been quoted on the NASDAQ Global Select Market under the symbol "NXTM" since January 3, 2010 and prior to that was quoted on the NASDAQ Global Market since July 1, 2006 and the NASDAQ National Market since October 27, 2005. Prior to that time, there was no public market for our stock. The following table sets forth, for the periods indicated, the high and low closing sale prices of our common stock.

	<u>High</u>	<u>Low</u>
2010		
First Quarter	\$11.45	\$ 7.69
Second Quarter	\$15.50	\$10.96
Third Quarter	\$19.40	\$13.59
Fourth Quarter	\$24.88	\$19.35
2009		
First Quarter	\$ 3.98	\$ 2.11
Second Quarter	\$ 5.90	\$ 1.93
Third Quarter	\$ 7.04	\$ 4.64
Fourth Quarter	\$ 8.43	\$ 5.39

Holders

On February 9, 2011, the last reported sale price of our common stock was \$21.81 per share. As of February 9, 2011, there were approximately 76 holders of record of our common stock and approximately 2,500 beneficial holders of our common stock.

Dividends

We have never paid or declared any cash dividends on our common stock. We anticipate that we will retain our earnings for future growth and therefore do not anticipate paying cash dividends in the future. Our loan agreements with Asahi and SVB restrict our ability to pay dividends.

Issuer Purchases of Equity Securities

During 2010, we received 288,992 shares of our common stock that were surrendered by employees in payment for the minimum required withholding taxes associated with awards under our 2009 Corporate Bonus and Performance Share Plans and 36,112 shares that were surrendered in payment for the exercise of stock options. See Note 15 to the consolidated financial statements for the year ended December 31, 2010 included in this Annual Report on Form 10-K for further information.

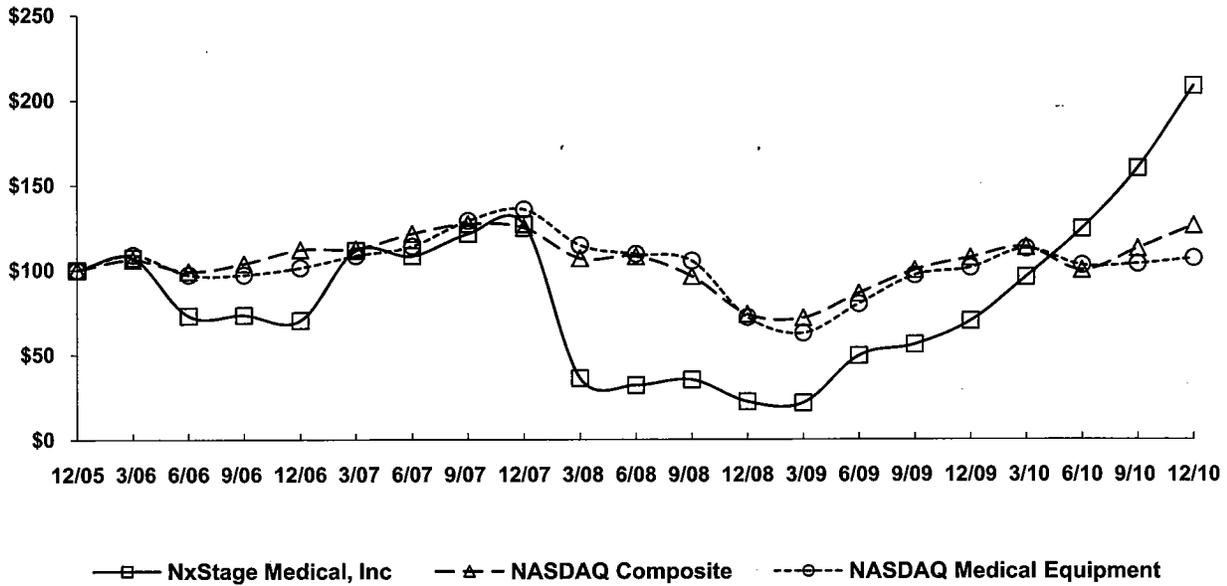
Comparative Stock Performance Graph

The following performance graph and related information shall not be deemed "soliciting material" or to be "filed" with the Securities and Exchange Commission, nor shall such information be incorporated by reference into any future filing under the Securities Act of 1933 or Securities Exchange Act of 1934, each as amended, except to the extent that we specifically incorporate it by reference into such filing.

The comparative stock performance graph below compares the cumulative stockholder return on our common stock for the period from December 31, 2005 through December 31, 2010 with the cumulative total return on (i) the Total Return Index for the NASDAQ Stock Market (U.S. Companies), which we refer to as

the NASDAQ Composite Index, and (ii) the NASDAQ Medical Equipment Index. This graph assumes the investment of \$100 on December 31, 2005 in our common stock, the NASDAQ Composite Index and the NASDAQ Medical Equipment Index and assumes all dividends are reinvested. Measurement points are the last trading days of the three month period ended March 31, June 30, September 30, and December 31, during 2010, 2009, 2008, 2007 and 2006.

COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN*
Among NxStage Medical, Inc, The NASDAQ Composite Index
And The NASDAQ Medical Equipment Index



* \$100 invested on 12/31/05 in stock or index, including reinvestment of dividends.
 Fiscal year ending December 31.

Item 6. Selected Financial Data

SELECTED CONSOLIDATED FINANCIAL DATA

The following selected consolidated financial data should be read together with the information under “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our consolidated financial statements and the notes to those consolidated financial statements included elsewhere in this Annual Report. The selected statements of operations data for the years ended December 31, 2010, 2009 and 2008 and balance sheet data as of December 31, 2010 and 2009 set forth below have been derived from our audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K. The selected statements of operations data for the years ended December 31, 2007 and 2006 and balance sheet data as of December 31, 2008, 2007 and 2006 set forth below have been derived from the audited consolidated financial statements for such years not included in this Annual Report.

	Years Ended December 31,				
	2010	2009	2008	2007	2006
	(In thousands, except per share data)				
Statement of Operations Data:					
Revenues	\$179,218	\$148,676	\$128,763	\$ 59,964	\$ 20,812
Cost of revenues	<u>121,091</u>	<u>111,812</u>	<u>108,387</u>	<u>65,967</u>	<u>26,121</u>
Gross profit (deficit)	<u>58,127</u>	<u>36,864</u>	<u>20,376</u>	<u>(6,003)</u>	<u>(5,309)</u>
Operating expenses:					
Selling and marketing	34,166	30,047	27,965	21,589	14,356
Research and development	12,900	9,814	8,890	6,335	6,431
Distribution	14,751	13,918	14,267	13,111	7,093
General and administrative	<u>22,774</u>	<u>19,532</u>	<u>19,239</u>	<u>13,046</u>	<u>8,703</u>
Total operating expenses	<u>84,591</u>	<u>73,311</u>	<u>70,361</u>	<u>54,081</u>	<u>36,583</u>
Loss from operations	(26,464)	(36,447)	(49,985)	(60,084)	(41,892)
Other (expense) income, net	<u>(4,480)</u>	<u>(6,755)</u>	<u>(852)</u>	<u>1,750</u>	<u>2,262</u>
Net loss before income taxes	(30,944)	(43,202)	(50,837)	(58,334)	(39,630)
Provision for income taxes	<u>768</u>	<u>265</u>	<u>374</u>	<u>62</u>	<u>—</u>
Net loss	<u>\$ (31,712)</u>	<u>\$ (43,467)</u>	<u>\$ (51,211)</u>	<u>\$ (58,396)</u>	<u>\$ (39,630)</u>
Net loss per share, basic and diluted	<u>\$ (0.66)</u>	<u>\$ (0.93)</u>	<u>\$ (1.23)</u>	<u>\$ (1.86)</u>	<u>\$ (1.60)</u>
Weighted-average shares outstanding, basic and diluted	<u>48,188</u>	<u>46,627</u>	<u>41,803</u>	<u>31,426</u>	<u>24,817</u>

	December 31,				
	2010	2009	2008	2007	2006
	(In thousands)				

Balance Sheet Data:

Cash, cash equivalents and short-term investments	\$ 104,339	\$ 21,720	\$ 26,642	\$ 34,345	\$ 61,802
Working capital	119,089	36,037	34,362	40,655	64,716
Total assets	286,094	196,978	212,066	210,386	101,725
Long-term liabilities	97,574	78,267	52,580	46,134	5,495
Accumulated deficit	(308,426)	(276,714)	(233,247)	(182,036)	(123,640)
Total stockholders’ equity(1)(2)(3)(4)(5)	152,129	89,446	122,447	129,717	83,409

(1) In November 2010, we issued and sold 3.7 million shares of common stock pursuant to an underwriting agreement with Canaccord Genuity. Net proceeds from the sale were \$73.4 million.

- (2) In May 2008, we issued and sold 5.6 million unregistered shares of common stock and warrants to purchase 1.1 million shares of our common stock. In August 2008, we issued and sold an additional 4.0 million share of common stock and warrants to purchase 0.8 million shares of our common stock. The aggregate net proceeds of both sales was \$42.3 million.
- (3) On October 1, 2007, we issued 6.5 million shares of common stock at \$12.50 per share in connection with the Medisystems Acquisition.
- (4) On February 7, 2007, we issued and sold to DaVita 2.0 million shares of common stock at a purchase price of \$10.00 per share, for net proceeds of \$19.9 million.
- (5) We closed our follow-on public offering on June 14, 2006, which resulted in the issuance of 6.3 million shares of common stock at \$8.75 per share. Net proceeds from the offering were \$51.3 million.

Item 7. *Management's Discussion and Analysis of Financial Condition and Results of Operation*

Overview

We report the results of our operations in two segments: the System One segment and the In-Center segment. We distribute our products in three markets: home, critical care and in-center. Within the System One segment, we offer a similar technology platform of the System One for the home and critical care markets with different features. We offer primarily needles and blood tubing sets in the In-Center segment. Our products are predominantly used by our customers to treat patients suffering from ESRD or acute kidney failure. We have marketing and sales efforts dedicated to each market, although nearly all sales in the In-Center segment are made through distributors.

During 2010, we grew our revenues by 21% from \$148.7 million during 2009 to \$179.2 million during 2010, with growth occurring in each market: home, critical care and in-center. In the home market, revenues increased \$22.3 million, or 35%, during 2010 compared to 2009, with the significant majority resulting from an increase in the number of patients prescribed to use and centers offering the System One. During 2010, we increased both the average number of patients at existing centers and the number of total centers offering the System One, through new and existing relationships with service providers, including DaVita and Fresenius. Critical care market revenues increased \$5.8 million, or 26%, during 2010 compared to 2009, primarily due to increased sales of the System One resulting from our efforts to increase our market share and increased sales of disposables from our growing installed base of System One equipment. In 2011, we expect to see continued growth in our revenues, primarily driven by the System One segment due to the annuity nature of our business, as well as the life-sustaining, non-elective nature of dialysis therapy. Our two largest customers in the home market, DaVita and Fresenius, will be important to that growth. If the purchasing patterns of either of these customers adversely change, our business will be adversely affected, at least in the near term. In-center revenues increased \$2.5 million, or 4%, during 2010 compared to 2009. The increase was driven by increased sales of our needle products. We expect future demand will continue to be susceptible to fluctuation as a result of increased competition and variations in inventory management policies with both our distributors and end users.

We continue to see improvements in our financial performance below the revenue line. We have not yet achieved profitable operating margins, but we continue to improve gross margins and cash flows from operating activities. We have consistently improved gross margin on a quarterly and annual basis from 16% during 2008 to 25% during 2009 to 32% during 2010. The improvements in gross margin were primarily driven by lower overall costs of revenues resulting from improvements in product design and reliability, leveraging our manufacturing infrastructure, transition of manufacturing and equipment service to lower cost labor markets and pricing strategies. During 2010, cash flows from operating activities were positive due to improvements in net loss versus 2009 and a \$4.3 million one-time customer prepayment on first quarter 2011 orders. While we expect to see continued improvements to our cash flows from operating activities, driven in meaningful part through continued improvement in our gross profits, in the near term, we expect cash flows from operating activities on a quarterly basis to fluctuate between negative and positive, primarily due to changes in working capital. We are encouraged by the improvements to our operating margins and are continuing to work hard toward our long-term goal of achieving profitable operating margins. However, there

can be no assurance that we will be able to continue to improve our operating margins or achieve positive operating margins. Our ability to become profitable and, its timing and sustainability, depend principally upon continued improvements in gross margins, growing revenues, and leverage of our operating infrastructure including any investment in selling and marketing or research and development activities.

Statement of Operations Components

Revenues

In the System One segment we derive our revenues from the sale and rental of equipment and the sale of disposable products in the home and critical care markets. In the home market, customers purchase or rent the System One equipment, including cyclers and PureFlow SL, and then purchase the related disposable products based on a specific patient prescription. In the critical care market, we sell or rent the System One and related disposables to hospital customers. In the In-Center segment, we derive our revenues from the sale of needles and blood tubing sets. Nearly all of our sales in the In-Center segment are through supply and distribution contracts with distributors.

In the home market the majority of our revenue is derived from recurring sales of disposable products. For customers that purchase the System One, we recognize revenue from the equipment sale ratably over the expected service obligation period. For customers that rent the System One, we recognize revenue on a monthly basis. We recognize revenues related to the disposable products upon delivery. Over time, as more home patients are treated with the System One and more systems are placed in patient homes, we expect to derive a growing recurring revenue stream from the sale of related disposables.

Our contracts with dialysis centers in the home market for ESRD home dialysis patients generally include terms providing for the sale of disposable products to accommodate up to the number of prescribed treatments per month per patient and the purchase or monthly rental of System One cyclers and, in most instances, our PureFlow SL hardware. These contracts typically have a term of one to seven years, and may be renewed on a month-to-month basis thereafter, subject to a 30-day termination notice. Under these contracts, if home hemodialysis is prescribed, supplies are shipped directly to patient homes and paid for by the treating dialysis center. We also include vacation delivery terms, providing for the shipment of products to a designated vacation destination for a specified number of vacation days. We derive a small amount of revenues from the sale of supplementary products and services such as ancillaries, reserve inventory and special deliveries.

In the critical care market we recognize revenues from direct product sales at the time of shipment or, if applicable, delivery in accordance with contract terms. Our contracts with hospitals generally include terms providing for the sale of our System One hardware and disposables, although we also provide a hardware rental option. These contracts typically have a term of one year. We derive a small amount of revenues from the sale of one-and two-year service contracts following the expiration of our standard one-year warranty period for System One hardware. To further support service in the critical care market, we have a bio-medical training program, whereby we train bio-medical engineers on how to service and repair certain aspects of the System One in the critical care setting. Bio-medical training is typically provided under a two-year contract following the expiration of our standard one-year warranty period for System One hardware. As more System One equipment is placed within hospitals, we expect to derive a growing recurring revenue stream from the sale of disposable cartridges and fluids as well as, to a much lesser degree, from the sale of service and bio-medical training contracts.

In the In-Center segment, nearly all sales to end users are structured through supply and distribution contracts with several significant distributors. These contracts typically contain minimum volume commitments with negotiated pricing triggers at different volume tiers. Each agreement may be cancelled upon a material breach, subject to certain cure rights, and in many instances minimum volume commitments can be reduced or eliminated upon certain events.

In addition to contractually determined volume discounts, we offer certain customers rebates based on sales to specific end users and discounts for early payment. Our revenues are presented net of these rebates and discounts. As of December 31, 2010, we had \$1.4 million and \$0.5 million reserved against trade accounts

receivable for future rebates and discounts for customers in our In-Center and System One segments, respectively. We recorded \$5.5 million, \$8.6 million and \$7.3 million during 2010, 2009 and 2008, respectively, as a reduction of In-Center segment revenues and \$2.3 million, \$1.2 million and \$0.7 million during 2010, 2009 and 2008, respectively, as a reduction of System One segment revenues in connection with rebates and discounts.

Currently nearly all of our revenues have been generated from sales to customers in the U.S. However, in 2009 we began selling our System One and certain of our other products internationally through distributors. For sales to our international distributors, we recognize revenues from the equipment sale ratably over the expected term of our remaining obligation, which is typically five years. We recognize revenues related to the disposable products upon delivery. However, effective January 1, 2011, we adopted two new Accounting Standard Updates, or ASUs, which will affect revenue recognition for sales to our international distributors within the System One segment. Under the new ASUs, for international sales beginning January 1, 2011, we will recognize revenues from equipment sales to international distributors at the time of shipment or, if applicable, delivery in accordance with contract terms. We will adopt the new ASUs prospectively and therefore, equipment shipped prior to January 1, 2011 will continue to be recognized as revenues ratably.

Cost of Revenues

Cost of revenues consists primarily of direct product costs, material and labor required to manufacture our products, service of System One equipment that we sell or rent to customers and manufacturing overhead. It also includes the cost of inspecting, servicing and repairing System One equipment prior to sale or during the warranty period and stock-based compensation for certain personnel. The cost of our products depends on several factors, including the efficiency of our manufacturing operations, the cost at which we can obtain labor and products from third-party suppliers, product reliability and related servicing costs and the design of our products.

Operating Expenses

Selling and Marketing. Selling and marketing expenses consist primarily of salary, benefits and stock-based compensation for sales and marketing personnel, travel, promotional and marketing materials and other expenses associated with providing clinical training to our customers. Included in selling and marketing are the costs of clinical educators, usually nurses, we employ to teach our customers about our products and prepare our customers to instruct their patients and their partners in the operation of our products and customer service and technical support personnel.

Research and Development. Research and development expenses consist primarily of salary, benefits and stock-based compensation for research and development personnel, supplies, materials and expenses associated with product design and development, clinical studies, regulatory submissions, reporting and compliance and expenses incurred for outside consultants or firms who furnish services related to these activities.

Distribution. Distribution expenses include the freight costs of delivering our products to our customers or our customers' patients, depending on the market and the specific agreements with our customers, salary, benefits and stock-based compensation for distribution personnel and the cost of any equipment lost or damaged in the distribution process. We use common carriers and freight companies to deliver our products and do not operate our own delivery service. Also included in this category are the expenses of shipping products under warranty from customers back to our service center for repair and the related expense of shipping a replacement product to our customers or their patients.

General and Administrative. General and administrative expenses consist primarily of salary, benefits and stock-based compensation for our executive management, legal and finance and accounting staff, fees of outside legal counsel, fees for our annual audit and tax services, and general expenses to operate the business, including insurance and other corporate-related expenses.

Results of Operations

The following table presents, for the periods indicated, information expressed as a percentage of revenues. This information has been derived from our consolidated statements of operations included elsewhere in this Annual Report on Form 10-K. You should not draw any conclusions about our future results from the results of operations for any period.

	Years Ended December 31,		
	2010	2009	2008
Revenues	100%	100%	100%
Cost of revenues	68%	75%	84%
Gross profit	32%	25%	16%
Operating expenses:			
Selling and marketing	19%	20%	22%
Research and development	7%	7%	7%
Distribution	8%	9%	11%
General and administrative	13%	13%	15%
Total operating expenses	47%	49%	55%
Loss from operations	(15)%	(24)%	(39)%
Other expense:			
Interest income	0%	0%	0%
Interest expense	(3)%	(5)%	(3)%
Other income (expense), net	0%	0%	0%
Change in fair value of financial instruments	0%	0%	2%
	(3)%	(5)%	(1)%
Provision for income taxes	0%	0%	0%
Net loss	(18)%	(29)%	(40)%

Comparison of Years Ended December 31, 2010 and 2009

Revenues

Our revenues for 2010 and 2009 were as follows (in thousands, except percentages):

	Years Ended December 31,			
	2010		2009	
System One segment				
Home	\$ 85,762	48%	\$ 63,461	43%
Critical Care	28,093	16%	22,340	15%
Total System One segment	113,855	64%	85,801	58%
In-Center segment	65,363	36%	62,875	42%
Total	\$179,218	100%	\$148,676	100%

The increase in revenues was mainly attributable to increased sales and rentals of the System One and related disposables in both the home and critical care markets, primarily as a result of the growing number of patients using the System One as we continue to penetrate these markets.

In the home market, revenues increased \$22.3 million, or 35%, during 2010 compared to 2009, with the significant majority resulting from an increase in the number of patients prescribed to use and centers offering

the System One. During 2010, we increased both the average number of patients at existing centers and the number of total centers offering the System One, through new and existing relationships with service providers, including DaVita and Fresenius. Critical care market revenues increased \$5.8 million, or 26%, during 2010 compared to 2009, primarily due to increased sales of the System One resulting from our efforts to further penetrate the market and increased sales of disposables from our growing number of System One equipment placed within hospitals. Growth in the critical care market in 2010 also benefitted from slightly improved economic conditions compared to 2009. Future demand for our products in both the home and critical care markets is expected to remain strong due to the life-sustaining, non-elective nature of dialysis therapy. As we further penetrate these markets and as we expand internationally, we expect revenues in the home and critical care markets to continue to increase.

In-Center segment revenues increased \$2.5 million, or 4%, during 2010 compared to 2009. The increase in revenues was due to increased sales of our needles. We expect future demand will continue to be susceptible to fluctuation as a result of increased competition and variations in inventory management policies with both our distributors and end users.

Gross Profit

Our gross profit and gross profit as a percentage of revenues for 2010 and 2009 were as follows (in thousands, except percentages):

	Years Ended			
	December 31, 2010	% Revenues	December 31, 2009	% Revenues
System One segment	\$42,620	37%	\$21,263	25%
In-Center segment	15,507	24%	15,601	25%
Gross Profit	<u>\$58,127</u>	32%	<u>\$36,864</u>	25%

The increase in gross profit was a result of increased revenues and improvement in gross profit as a percentage of revenues. The improvement in gross profit as a percentage of revenues was attributable to improvements in the System One segment, specifically, lower costs resulting from certain costs saving initiatives and improvements in product design, decreased equipment service costs per unit resulting from improved product reliability, lower overall cost of manufacturing as we continue to realize the benefits of leveraging our manufacturing infrastructure, increased relative sales of higher margin products and certain pricing strategies.

Gross profit for the In-Center segment decreased slightly in absolute dollars and as a percentage of revenues during 2010 compared to 2009, due to costs incurred related to manufacturing process improvements to support future growth.

We expect gross profit as a percentage of revenues will continue to improve over time for three general reasons, all of which we expect will reduce costs in the future. First, we expect to introduce additional process improvements and product design changes that have inherently lower cost than our current products. Second, we anticipate that increased sales volume and realization of economies of scale will lead to better purchasing terms and prices and efficiencies in manufacturing and supply chain overhead costs. Finally, we expect to continue to improve product reliability, which would reduce unit service costs. Additionally, given the longevity of certain of our System One field equipment assets, in the fourth quarter of 2010 we changed the estimated useful life of these assets from five to seven years which will result in lower field equipment depreciation costs in the near term. However, there is no certainty that our expectations will be achieved with respect to these cost reduction plans.

Selling and Marketing

Our selling and marketing expenses for 2010 and 2009 were as follows (in thousands, except percentages):

	Years Ended		Change	Percentage Change
	December 31, 2010	December 31, 2009		
System One segment	\$29,377	\$26,144	\$3,233	12%
In-Center segment	4,789	3,903	886	23%
Total Selling and marketing	<u>\$34,166</u>	<u>\$30,047</u>	<u>\$4,119</u>	14%

The increase in selling and marketing expense was primarily the result of increased personnel and personnel-related costs, primarily non-cash stock-based compensation expenses, and increased spending due to expanded marketing programs. We anticipate that selling and marketing expenses will continue to increase in absolute dollars but continue to decline as a percentage of revenues as we broaden our marketing initiatives to increase public awareness of the System One in the home market and to support growth in international markets.

Research and Development

Our research and development expenses for 2010 and 2009 were as follows (in thousands, except percentages):

	Years Ended		Change	Percentage Change
	December 31, 2010	December 31, 2009		
Research and development	<u>\$12,900</u>	<u>\$9,814</u>	<u>\$3,086</u>	31%

Research and development expenses increased in absolute dollars but remained consistent as a percentage of revenues at 7% for both 2010 and 2009. The increase in research and development expenses was primarily due to increased personnel and personnel-related costs, primarily non-cash stock-based compensation expense and increased project related spending. This increase was partially offset by a decrease in clinical trials expenses primarily related to our nocturnal IDE as we completed the study in February 2010. For the near term, we expect research and development expenses will increase in absolute dollars but remain relatively constant as a percentage of revenues as we seek to further enhance and improve the reliability of our System One and related products and as we continue with our FREEDOM study, which is designed to quantify the clinical benefits and costs of daily home therapy administered to Medicare patients using the System One versus conventional thrice-weekly dialysis.

Distribution

Our distribution expenses for 2010 and 2009 were as follows (in thousands, except percentages):

	Years Ended		Change	Percentage Change
	December 31, 2010	December 31, 2009		
System One segment	\$12,960	\$12,564	\$396	3%
In-Center segment	1,791	1,354	437	32%
Total Distribution	<u>\$14,751</u>	<u>\$13,918</u>	<u>\$833</u>	6%

Distribution expenses decreased as a percentage of revenues to 8% for 2010 versus 9% for 2009. Distribution expenses for the System One segment decreased as a percentage of revenues to 11% for 2010 versus 15% for 2009, due primarily to efficiencies gained from economies of scale resulting from increased business volume, improved product reliability of our System One and PureFlow SL hardware and better pricing obtained from carriers. Distribution expenses as a percentage of revenues for the In-Center segment

increased slightly to 3% for 2010 versus 2% for 2009, due primarily to increased delivery costs for certain products shipped from our international manufacturing locations to our customers. We expect that distribution expenses in absolute dollars will fluctuate modestly from period to period driven in large part by changes in fuel prices but, overall, we expect distribution expenses will increase at a lower rate than revenues due to expected efficiencies gained from increased business volume and improved reliability of System One equipment.

General and Administrative

Our general and administrative expenses for 2010 and 2009 were as follows (in thousands, except percentages):

	Years Ended		Change	Percentage Change
	December 31, 2010	December 31, 2009		
General and administrative	\$22,774	\$19,532	\$3,242	17%

General and administrative expenses increased in absolute dollars but remained consistent as a percentage of revenues at 13% for both 2010 and 2009. The increase in general and administrative expenses was primarily the result of increased personnel and personnel-related costs, primarily non-cash stock-based compensation expenses. These increases were offset by lower spending on corporate support functions, including consulting and other professional services, due to our continued initiatives to control costs. We expect that general and administrative expenses will decrease as a percentage of revenues over time as we continue to leverage our existing infrastructure.

Other Income and Expense

Interest income is derived primarily from investments in money market funds. The decrease in interest income is due to lower interest rates on investments.

Interest expense decreased \$1.9 million during 2010 compared to 2009, due primarily to prepayment and other transaction fees of \$2.0 million incurred during 2009 to pay off the entire debt obligation owed under our credit and security agreement with General Electric Capital Corporation, or GE.

The change in other expense during both periods is derived primarily by foreign currency gains and losses.

Provision for Foreign Income Taxes

The provision for income taxes of \$0.8 million in 2010 and \$0.3 million in 2009 relates primarily to the profitable operations of certain of our foreign entities.

Comparison of Years Ended December 31, 2009 and 2008

Revenues

Our revenues for 2009 and 2008 were as follows (in thousands, except percentages):

	Years Ended December 31,			
	2009		2008	
System One segment				
Home	\$ 63,461	43%	\$ 48,319	38%
Critical Care	22,340	15%	18,554	14%
Total System One segment	85,801	58%	66,873	52%
In-Center segment	62,875	42%	61,890	48%
Total	\$148,676	100%	\$128,763	100%

The increase in revenues was attributable to increased sales and rentals of the System One and related disposables in both the home and critical care markets, primarily as a result of the growing number of patients using the System One as we continue to penetrate the market place, and an increase in sales of blood tubing sets in our In-Center segment.

In the home market, revenues increased \$15.1 million, or 31%, in 2009 compared to 2008 as a result of an increase in the number of patients prescribed to use and centers offering the System One. During 2009 we increased the average number of patients at existing centers and the number of total centers offering the System One. Critical care market revenues increased \$3.8 million, or 20%, in 2009 compared to 2008, primarily as a result of sales of additional System One units, the growth of our installed base of units and the associated sales of disposables due to our efforts to continue to penetrate the market. In-Center segment revenues increased \$1.0 million, or 2%, in 2009 compared to 2008. The increase in revenues was due to higher sales volumes of our blood tubing sets, including Streamline, our newest blood tubing set.

Gross Profit

Our gross profit and gross profit as a percentage of revenues for 2009 and 2008 were as follows (in thousands, except percentages):

	Years Ended			
	December 31, 2009	% Revenues	December 31, 2008	% Revenues
System One segment	\$21,263	25%	\$ 8,960	13%
In-Center segment	15,601	25%	11,416	18%
Gross Profit	<u>\$36,864</u>	25%	<u>\$20,376</u>	16%

The increase in gross profit was a result of increased revenues and improvement in gross profit as a percentage of revenues. The improvement in gross profit as a percentage of revenues was primarily attributable to the System One segment, specifically, lower costs resulting from improvements in reliability and equipment utilization and lower overall costs of manufacturing as we continue to realize the benefits of leveraging our manufacturing infrastructure, certain cost saving initiatives such as the transition of manufacturing and equipment service to lower cost labor markets, and improvements in product design and reliability. Gross profit as a percentage of revenues for the In-Center segment increased during 2010 compared to 2009, due to lower manufacturing costs resulting from the benefits of certain manufacturing process improvements and product design improvements.

Selling and Marketing

Our selling and marketing expenses for 2009 and 2008 were as follows (in thousands, except percentages):

	December 31, 2009	December 31, 2008	Change	Percentage Change
System One segment	\$26,144	\$24,491	\$1,653	7%
In-Center segment	3,903	3,474	429	12%
Total Selling and marketing	<u>\$30,047</u>	<u>\$27,965</u>	<u>\$2,082</u>	7%

The increase in selling and marketing expenses was primarily the result of increased personnel and personnel-related costs, including non-cash stock-based compensation expense due to expanded sales and marketing and customer service functions.

Research and Development

Our research and development expenses for 2009 and 2008 were as follows (in thousands, except percentages):

	Years Ended		Change	Percentage Change
	December 31, 2009	December 31, 2008		
Research and development	<u>\$9,814</u>	<u>\$8,890</u>	<u>\$924</u>	10%

The increase in research and development expenses was primarily a result of increased personnel and personnel-related costs, including non-cash stock-based compensation expense, due to increased headcount. Additionally, expenses for clinical trials have increased due to increased patient enrollment in our nocturnal IDE and FREEDOM studies.

Distribution

Our distribution expenses for 2009 and 2008 were as follows (in thousands, except percentages):

	Years Ended		Change	Percentage Change
	December 31, 2009	December 31, 2008		
System One segment	\$12,564	\$12,631	\$(67)	(1)%
In-Center segment	<u>1,354</u>	<u>1,636</u>	<u>(282)</u>	(17)%
Total Distribution	<u>\$13,918</u>	<u>\$14,267</u>	<u>\$(349)</u>	(2)%

The decrease in distribution expenses was primarily a result of better pricing obtained from carriers and shipping efficiencies. Distribution expenses for the System One segment remained relatively consistent year over year but decreased as a percentage of revenues from 19% during 2008 to 15% during 2009, due primarily to better pricing obtained from carriers, shipping efficiencies and improved reliability of our System One and PureFlow SL hardware. Distribution expenses for the In-center segment decreased due to shipping efficiencies.

General and Administrative

Our general and administrative expenses for 2009 and 2008 were as follows (in thousands, except percentages):

	Years Ended		Change	Percentage Change
	December 31, 2009	December 31, 2008		
General and administrative	<u>\$19,532</u>	<u>\$19,239</u>	<u>\$293</u>	2%

General and administrative expenses increased year over year but decreased as a percentage of revenue from 15% during 2008 to 13% during 2009 due to our continued initiative to leverage our overhead structure. The increase in general and administrative expenses was primarily a result of increased personnel and personnel related costs, including non-cash stock-based compensation expense, offset by a decreases in external services expense resulting from cost savings measures.

Other Income and Expense

Interest income decreased \$0.5 million in 2009 compared to 2008 due to lower interest rates on investments. Interest income is derived primarily from investments in money market funds.

Interest expense increased \$2.9 million in 2009 compared to 2008 due primarily to prepayment and other transaction fees of \$2.0 million incurred during 2009 to pay off the entire debt obligation owed under our credit and security agreement with GE and an increase in outstanding borrowings.

The change in other expense during both periods is derived primarily by foreign currency gains and losses.

The change in fair value of the warrants issued on May 22, 2008 and August 1, 2008 in connection with the private placement resulted in the recognition of a \$3.2 million gain and the change in fair value of the obligation entered into on May 22, 2008 in connection with the second tranche resulted in the recognition of a \$0.7 million loss during 2008. The obligation relating to the second tranche was settled on August 1, 2008 and the fair value on settlement of \$0.6 million was recorded in equity. The exercise price of the warrants was fixed at \$5.50 per share on December 31, 2008 based on the Company's ability to achieve over 3,100 ESRD patients prescribed to receive therapy using the System One. As a result, beginning January 1, 2009, the warrants were classified in equity and thereafter, no longer result in the recognition of changes in fair value in earnings. See Note 15 to the consolidated financial statements for the year ended December 31, 2009 included in this Annual Report on Form 10-K for further information.

Provision for Foreign Income Taxes

The provision for income taxes of \$0.3 million in 2009 and \$0.4 million in 2008 relates primarily to the profitable operations of certain of our foreign entities.

Liquidity and Capital Resources

We have operated at a loss since our inception in 1998. As of December 31, 2010, our accumulated deficit was \$308.4 million and we had cash and cash equivalents of \$104.3 million and working capital of \$119.1 million.

Our primary ongoing cash requirements will be to fund operating activities, product development and debt service. Our primary sources of liquidity are cash on hand and ongoing revenues. Historically, our business was fairly capital intensive due to the manner in which we placed our System One equipment in the home market. Prior to 2007, the significant majority of our System One placements in the home market were made under a rental model rather than an outright sale. Over the last three years, we have increased the number of System Ones we have sold versus rented, and in 2010, the significant majority of our System One placements in the home market were made under a sale versus rental model. Shifting our customers to an equipment purchase versus rental model allows us to recover the cost of our products upon initial sale rather than over an extended period of time, thereby reducing our working capital requirements. A number of our home market customers, including DaVita, have committed to purchase, rather than rent, the significant majority of their future System One equipment requirements. However, there can be no assurance that we will be able to continue to expand or sustain the percentage of our equipment placements that are purchased rather than rented. Other significant factors affecting the management of our ongoing cash requirements are our ability to continue to effectively manage our field equipment assets and working capital and execute upon cost reduction initiatives to lower product cost.

For the year ended December 31, 2010, cash flows from operating activities were positive due to improvements in net loss versus 2009 and a \$4.3 million one-time customer prepayment on first quarter 2011 orders. While we continue to make progress in improving our cash flows from operating activities, we expect cash flows from operating activities in the near term to fluctuate between negative and positive on a quarterly basis, primarily due to changes in working capital. There can be no assurance that we will be able to continue to improve cash flows from operating activities or whether we will be able to generate positive cash flows from operating activities in the future. We believe, based on current projections and the current nature of our business, that we have the required resources to fund our ongoing operating requirements. Our ability to and the rate at which we continue to improve cash flows from operating activities will depend on many factors, including growing revenues, continued improvements in gross margins, leverage of our operating infrastructure and continued sale versus rental of a significant percentage of our System One equipment.

We materially improved our cash position in 2010 through the completion of the registered sale of 3,680,000 shares of our common stock pursuant to an underwriting agreement with Canaccord Genuity. We received proceeds of \$73.4 million, net of related expenses, from this offering. The shares issued in this

offerings were registered under a registration statement on Form S-3, which became effective on November 17, 2010. This registration statement allows for the potential future registered sale by us of various other equity and debt securities, although we have no current plans to make such a future offering.

We have two material debt instruments. In May 2009, we entered into a term loan and security agreement with Asahi. The \$40.0 million term loan bears interest at a rate of 8% per annum, with fifty percent of such interest being deferred until the maturity date on May 31, 2013. Principal is payable in one balloon payment at maturity. The term loan is secured by substantially all of our assets. In the event the term loan reaches maturity, Asahi may require that all of the principal and interest on the term loan that is unpaid as of the maturity date be converted into shares of our common stock, with the number of shares to be determined based upon the average closing stock price of our common stock during the thirty business days preceding the maturity date, subject to certain conditions. We used \$30.0 million of the proceeds to pay off the entire debt obligation, including prepayment and other transaction fees, owed under our prior credit and security agreement with General Electric Capital Corporation.

The term loan and security agreement with Asahi includes certain affirmative covenants including timely filings and limitations on contingent debt obligations and sales of assets. At December 31, 2010, we were in compliance with these covenants. The term loan and security agreement also contains customary events of default, including nonpayment, misrepresentation, breach of covenants, material adverse effects, and bankruptcy. In the event we fail to satisfy our covenants, or otherwise go into default, Asahi has a number of remedies, including sale of our assets and acceleration of all outstanding indebtedness, subject to the rights of SVB's senior security interest. Any of these remedies would likely have a material adverse effect on our business.

We have the flexibility under our term loan with Asahi to seek up to \$40.0 million in additional debt at market interest rates. In March 2010, we entered into a Loan and Security Agreement with Silicon Valley Bank, or SVB, for a \$15.0 million revolving line of credit with a maturity date of April 1, 2012. This Agreement is secured by all or substantially all of our assets. In connection with this Agreement, we amended our term loan and security agreement with Asahi to provide for certain amendments, including granting to Asahi junior liens on certain of our assets for so long as the agreement with SVB remains outstanding. Upon termination of all obligations under that facility, Asahi's security will revert to a security in all assets other than cash, bank accounts, accounts receivable, field equipment and inventory. Borrowings under the Agreement bear interest at a floating rate per annum equal to two percentage points (2.00%) above the prime rate (initial prime rate of 4.00%). Pursuant to the Agreement, we have agreed to certain financial covenants relating to liquidity requirements and adjusted EBITDA, as defined in the Agreement with SVB. The Agreement contains events of default customary for transactions of this type, including nonpayment, misrepresentation, breach of covenants, material adverse effect and bankruptcy. At December 31, 2010, we were in compliance with the covenants, there were no outstanding borrowings and we had nearly all of the \$15.0 million credit commitment available for borrowing under the Agreement.

In May 2008, we entered into a \$43 million private placement agreement to sell an aggregate of 9.6 million shares of our common stock at a price of \$4.50 per share and warrants to purchase 1.9 million shares of our common stock at an exercise price of \$5.50 per share. The exercise price of the warrants was fixed at \$5.50 per share on December 31, 2008 based on the Company's ability to achieve over 3,100 ESRD patients prescribed to receive therapy using the System One. The warrants have a term of 5 years and expire on May 28, 2013 and August 1, 2013 for the first and second tranches respectively. The warrants also contain a net share settlement feature that is available to investors in the private placement once the underlying shares are registered. Additional provisions require the Company, in the event of a change of control, to pay promptly to the warrant holder an amount calculated by the Black-Scholes option pricing formula. Such payment is required to be in cash or shares in the same proportion that other stockholders receive in such change of control transaction.

We maintain postemployment benefit plans for employees in certain foreign subsidiaries. The plans provide lump sum benefits, payable based on statutory regulations for voluntary or involuntary termination. Where required, we obtain an annual actuarial valuation of the benefit plans. We have recorded a liability of

\$1.5 million as other long-term liabilities at December 31, 2010 for costs associated with these plans. The expense recorded in connection with these plans was not significant during 2010, 2009 and 2008.

The following table sets forth the components of our cash flows for the periods indicated (in thousands):

	Years Ended December 31,		
	2010	2009	2008
	(In thousands)		
Net cash provided by (used in) operating activities	\$ 3,111	\$(13,157)	\$(53,222)
Net cash used in investing activities	(1,216)	(2,065)	(457)
Net cash provided by financing activities	81,163	10,031	47,575
Foreign exchange effect on cash and cash equivalents	(439)	269	(499)
Net cash flow	<u>\$82,619</u>	<u>\$ (4,922)</u>	<u>\$ (6,603)</u>

Net Cash Provided by (Used in) Operating Activities. Net cash provided by operating activities was \$3.1 million during 2010, which represents a \$16.3 million improvement in cash flows from operating activities from 2009. The improvement during 2010 was attributable to three main factors. First, we improved our net loss after adjustments for non-cash charges as we continue to increase revenue and improve gross margins. Second, net deferred revenues increased \$11.8 million during 2010 as a result of the increase in the number of customers who chose to purchase, rather than rent, the System One equipment, which included amortization of deferred revenues totaling \$11.5 million during 2010. Currently, the majority of our System One placements in the home market are done under a sales versus rental model. Finally, working capital requirements increased, primarily due to inventory requirements, partially offset by a \$4.3 million one-time customer prepayment on first quarter 2011 orders. Net cash used in operating activities decreased \$40.1 million during 2009. The decrease in net cash used in operating activities during 2009 was primarily due to a decrease in our net loss after adjustments for non-cash charges as we continue to reduce product costs, and a decrease in inventory purchases for the production and placement of System One and PureFlow SL hardware as a result of reduced costs, improved reliability and improved management of our field equipment assets.

Non-cash transfers from inventory to field equipment for the placement of units with our customers increased \$10.3 million during 2010, to support the growing number of patients using the System One. Non-cash transfers from inventory to field equipment for the placement of units with our customers decreased \$11.5 million during 2009, due to improvements made in managing our field equipment assets, enabling us to continue to add patients without adding additional field equipment.

Non-cash transfers from field equipment to deferred costs of revenues increased \$13.8 million during 2010 and decreased \$5.4 million during 2009. This activity fluctuates based on the number of customers who choose to purchase rather than rent and customer conversions to purchasing from renting our System One equipment.

Net Cash Used in Investing Activities. For each of the periods above, net cash used in investing activities reflected purchases of property and equipment, primarily for manufacturing operations and capital improvements to our facilities, research and development and information technology. During 2008, net cash used in investing activities included \$1.1 million of proceeds from short-term investments and decreases in other assets.

Net Cash Provided by Financing Activities. Net cash provided by financing activities increased by \$71.1 million during 2010 and decreased by \$37.5 million during 2009. Net cash provided by financing activities during 2010 included net proceeds from the sale of our common stock of \$73.4 million and \$12.4 million of proceeds from stock option and stock purchase plans offset by cash used to repurchase shares of our common stock that were surrendered in payment for minimum required withholding taxes due on issuance of shares of our common stock under our 2009 Bonus Plan and vesting of restricted stock awards under our 2009 Performance Share Plan. Net cash provided by financing activities during 2009 included \$40.0 million of borrowings under our term loan with Asahi offset by \$0.1 million in fees paid in connection with the Asahi debt issuance, \$30.0 million in repayments of borrowings under our credit and security

agreement with GE and a \$0.5 million amendment fee paid in connection with the March 16, 2009 amendment to our credit and security agreement with GE. Net cash provided by financing activities during 2008 included \$5.0 million of additional borrowings under our credit and security agreement with GE and \$42.3 million net proceeds from the sale of 9.6 million shares of our common stock and warrants to purchase 1.9 million shares of our common stock.

Off-Balance Sheet Arrangements

Except for operating lease agreements, we do not have any off-balance sheet arrangements.

Contractual Obligations

The following table summarizes our contractual commitments as of December 31, 2010 and the effect those commitments are expected to have on liquidity and cash flow in future periods (in thousands):

	<u>Total</u>	<u>Less Than One Year</u>	<u>1-3 Years</u>	<u>3-5 Years</u>	<u>More Than 5 Years</u>
Debt obligations	\$ 51,621	\$ 1,665	\$49,956	\$ —	\$—
Operating leases	2,134	1,578	556	—	—
Purchase obligations	<u>63,933</u>	<u>39,443</u>	<u>21,322</u>	<u>3,168</u>	<u>—</u>
Total	<u>\$117,688</u>	<u>\$42,686</u>	<u>\$71,834</u>	<u>\$3,168</u>	<u>\$—</u>

Long-term debt obligations include the aggregate outstanding principal amount under our \$40.0 million term loan with Asahi and related deferred interest and estimated interest payments.

Our purchase obligations include purchase commitments for System One components, primarily for equipment, blood tubing sets, needles, and fluids pursuant to contractual agreements with several of our suppliers that are in the normal course of business. Certain of these commitments may be extended and/or canceled at our option.

Summary of Critical Accounting Policies and Estimates

Our discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States, or GAAP. The preparation of these consolidated financial statements requires us to make significant estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses. These items are regularly monitored and analyzed by management for changes in facts and circumstances, and material changes in these estimates could occur in the future. Changes in estimates are recorded in the period in which they become known. We base our estimates on historical experience and various other assumptions that we believe to be reasonable under the circumstances. Actual results may differ substantially from our estimates.

Note 2 to the consolidated financial statements for the year ended December 31, 2010 included in this Annual Report on Form 10-K describes the significant accounting policies used in the preparation of our consolidated financial statements. A summary of those accounting policies and estimates that we believe are most critical to fully understanding and evaluating our financial results is set forth below. This summary should be read in conjunction with our consolidated financial statements and the related notes included elsewhere in this Annual Report on Form 10-K.

Revenue Recognition

We recognize revenue from product sales and services when earned. Revenues are recognized when: (a) there is persuasive evidence of an arrangement, (b) the product has been shipped or services and supplies have been provided to the customer, (c) the sales price is fixed or determinable and (d) collection is reasonably assured. Our revenue arrangements with multiple elements are divided into separate units of accounting if specified criteria are met, including whether the delivered element has stand-alone value to the customer and

whether there is objective and reliable evidence of the fair value of the undelivered items. The consideration received is allocated among the separate units based on their respective fair values, and the applicable revenue recognition criteria are applied to each of the separate units.

Certain agreements with distributors allow for product returns and credits. For shipment of product sold to distributors, revenue is recognized at the time of sale if a reasonable estimate of future returns or refunds can be made. If a reasonable estimate of future returns or refunds cannot be made, we recognize revenue using the "sell-through" method. Under the "sell-through" method, revenue and related costs of revenue is deferred until the final resale of such products to end customers.

In addition to contractually determined volume discounts, in many agreements we offer rebates based on sales to specific end customers and discounts for early payment. Rebates and discounts are recorded as a reduction of sales and trade accounts receivable, based on our best estimate of the amount of probable future rebate or discount on current sales.

System One Segment

We derive revenue in the home market from the sales of hemodialysis therapy to customers in which the customer either purchases or rents the System One and/or PureFlow SL hardware and purchases a specified number of disposable products and, in some instances, service.

For customers that purchase the System One and PureFlow SL hardware, we must determine whether (a) the equipment has stand-alone value and (b) the fair value of the undelivered items, typically the disposables and, in most instances service, can be determined. If either criteria is not met, which is generally the case, the arrangement is accounted for as a single unit of accounting and the fees received upon the completion of delivery of equipment are deferred and recognized as revenue on a straight-line basis over the expected term of our remaining obligation and direct costs relating to the delivered equipment are amortized over the same period as the related revenue, while disposable products revenue is recognized on a monthly basis upon delivery. If both criteria are met, then the items are accounted for separately as delivered.

Under the rental arrangements revenue is recognized on a monthly basis in accordance with agreed upon contract terms and pursuant to binding customer purchase orders and fixed payment terms.

In the critical care market, we structure sales of the System One as direct product sales and have no significant post delivery obligations with the exception of standard warrant obligations. We recognize revenue from direct product sales at the time of shipment or, if applicable, delivery in accordance with contract terms.

Our contracts for the System One in the critical care market provide for training, technical support and warranty services to our customers. We recognize training and technical support revenue when the related services are performed. In the case of extended warranty, the service revenue is recognized ratably over the warranty period.

In-Center Segment

In the In-Center segment, nearly all sales to end users are structured through supply and distribution contracts with distributors. Some of our distribution contracts for the In-Center segment contain minimum volume commitments with negotiated pricing discounts at different volume tiers. Each agreement may be cancelled upon a material breach, subject to certain curing rights, and in many instances minimum volume commitments can be reduced or eliminated upon certain events.

Inventory Valuation

Inventories are valued at the lower of cost or estimated market. We regularly review our inventory quantities on hand and related cost and record a provision for excess or obsolete inventory primarily based on an estimated forecast of product demand for each of our existing product configurations. We also review our inventory value to determine if it reflects lower of cost or market, with market determined based on net realizable value. Appropriate consideration is given to inventory items sold at negative gross margins, purchase

commitments and other factors in evaluating net realizable value. The medical device industry is characterized by rapid development and technological advances as well as regulatory and quality manufacturing guidelines that could result in obsolescence of inventory. Additionally, our estimates of future product demand may prove to be inaccurate.

Field Equipment

Field equipment consists of equipment being utilized under disposable-based rental agreements as well as “service pool” cyclers. Service pool cyclers are cyclers owned and maintained by us that are swapped for cyclers that need repairs or maintenance by us while being rented or owned by a patient. We continually monitor the number of cyclers in the service pool, as well as cyclers that are in-transit or otherwise not being used by a patient, and assess whether there are any indicators of impairment for such equipment. We also review field equipment carrying value for reasonableness. We consider factors such as actual equipment disposals and our ability to verify the equipment’s existence in the field to identify lost equipment. Charges for lost equipment are included in distribution expenses.

We capitalize field equipment at cost and amortize field equipment through cost of revenues using the straight-line method over an estimated useful life. We review the estimated useful life of our field equipment periodically for reasonableness and make changes when appropriate. Factors considered in determining the reasonableness of the useful life include industry practice and the typical amortization periods used for like equipment, the frequency and scope of service returns and the impact of historical and planned future design improvements.

Accounting for Stock-Based Awards

Stock-based compensation expense is estimated as of the grant date based on the fair value of the award and is recognized as expense over the requisite service period, which generally equals the vesting period, based on the number of awards that are expected to vest. Estimating the fair value for stock options requires judgment, including the expected term of our stock options, volatility of our stock, expected dividends, risk-free interest rates over the expected term of the options and the expected forfeiture rate. In connection with our performance based programs, we make assumptions principally related to the number of awards that are expected to vest after assessing the probability that certain performance criteria will be met.

Valuation of Intangibles and Other Long-Lived Assets

For our long-lived assets including intangible assets, we assess the carrying value of these assets whenever events or changes in circumstances indicate that the carrying value may not be recoverable. Factors we consider important include, but are not limited to, significant underperformance relative to historical or projected future results, significant negative industry factors and significant changes in strategy or operations that negatively affect the utilization of our long-lived assets. If an impairment review is triggered, we evaluate the carrying value of intangible assets based on estimated undiscounted future cash flows over the remaining useful life of the assets and comparing that value to the carrying value of the assets. The amount of impairment, if any, is measured based on fair value, which is determined using projected discounted future operating cash flows. The cash flows that are used contain our best estimates, using appropriate and customary assumptions and projections at the time. If the cash flow estimates or the significant operating assumptions upon which they are based change in the future, we may be required to record additional impairment charges.

Goodwill

We assess goodwill for impairment annually in the fourth quarter and whenever events or circumstances indicate impairment may exist. Goodwill may be considered impaired if we determine that the carrying value of our reporting unit, including goodwill, exceeds the reporting unit’s fair value. Our reporting units are our System One and In-center operating segments. Assessing the impairment of goodwill requires us to make assumptions and judgments including the identification of reporting units and determination of the fair value of the net assets of our reporting units. We estimate reporting unit fair value using a discounted cash flow

approach which requires the use of assumptions and judgments including estimates of future cash flows and the selection of discount rates. Our annual impairment testing indicated no significant risk of impairment based upon changes in value that are reasonably likely to occur. However, changes in these estimates and assumptions could materially affect the estimated fair values of reporting units.

Accounting for Income Taxes

We periodically assess our income tax positions and record tax benefits for all years subject to examination based upon our evaluation of the facts, circumstances and information available at the reporting date. If our judgment as to the likely resolution of the position changes, if the matter is ultimately settled or if the statute of limitation expires, the effects of the change would be recognized in the period in which the change, resolution or expiration occurs.

We file federal, state and foreign tax returns based on our interpretation of tax laws and regulations and record estimates based on these judgments and interpretations. We have accumulated significant losses since our inception in 1998. Since the net operating losses may potentially be utilized in future years to reduce taxable income, all of our tax years remain open to examination by the major taxing jurisdictions to which we are subject.

Related-Party Transactions

A discussion of related-party transactions is included in Note 16 to the consolidated financial statements for the year ended December 31, 2010 included in this Annual Report on Form 10-K.

Recent Accounting Pronouncements

A discussion of recent accounting pronouncements is included in Note 2 to the consolidated financial statements for the year ended December 31, 2010 included in this Annual Report on Form 10-K.

Item 7A. *Quantitative and Qualitative Disclosures About Market Risk*

Interest Rate Exposure

Our investment portfolio consists primarily of money market funds. We manage our investment portfolio in accordance with our investment policy. The primary objectives of our investment policy are to preserve principal, maintain a high degree of liquidity to meet operating needs and obtain competitive returns subject to prevailing market conditions. Our investments are subject to changes in credit rating and changes in market value. These investments are also subject to interest rate risk and will decrease in value if market interest rates increase. Due to the conservative nature of our investments, we believe interest rate risk is mitigated. Our investment policy specifies the credit quality standards for our investments and limits the amount of exposure from any single issue, issuer or type of investment.

Foreign Currency Exposure

We operate a manufacturing and research facility in Germany as well as manufacturing facilities in Italy and Mexico. We purchase materials for those facilities and pay our employees at those facilities in Euros and Pesos. In addition, we purchase products for resale in the United States from foreign companies and have agreed to pay them in currencies other than the U.S. dollar, including the Euro and Peso. We also have contracts with key suppliers that expose us to foreign currency risks, including the Euro and the Thai Baht. As a result, our expenses and cash flows are subject to fluctuations due to changes in foreign currency exchange rates. In periods when the U.S. dollar declines in value as compared to the foreign currencies in which we incur expenses, our foreign-currency based expenses increase when translated into U.S. dollars. Although it is possible to do so and we may in the future, we do not currently hedge our foreign currency transactions since the exposure has not been material to our historical operating results. A 10% movement in the Euro, Peso and Baht would have an overall impact to the statement of operations of approximately \$4.5 million for 2010, which would have been approximately 2% of total annual expenses.

Item 8. *Financial Statements and Supplementary Data*

NXSTAGE MEDICAL, INC.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders of NxStage Medical, Inc.

We have audited the accompanying consolidated balance sheets of NxStage Medical, Inc. as of December 31, 2010 and 2009, and the related consolidated statements of operations, changes in stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2010. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of NxStage Medical, Inc. at December 31, 2010 and 2009, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2010, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), NxStage Medical, Inc.'s internal control over financial reporting as of December 31, 2010, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission and our report dated February 18, 2011 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Boston, Massachusetts
February 18, 2011

NXSTAGE MEDICAL, INC.
CONSOLIDATED BALANCE SHEETS

December 31,
2010 2009
(In thousands, except share
data)

ASSETS

Current assets:		
Cash and cash equivalents	\$ 104,339	\$ 21,720
Accounts receivable, net	14,107	14,238
Inventory	34,950	28,117
Prepaid expenses and other current assets	<u>2,084</u>	<u>1,227</u>
Total current assets	155,480	65,302
Property and equipment, net	8,290	10,336
Field equipment, net	13,660	21,726
Deferred cost of revenues	40,081	27,799
Intangible assets, net	25,412	28,208
Goodwill	42,698	42,698
Other assets	<u>473</u>	<u>909</u>
Total assets	<u>\$ 286,094</u>	<u>\$ 196,978</u>

LIABILITIES AND STOCKHOLDERS' EQUITY

Current liabilities:		
Accounts payable	\$ 16,811	\$ 19,827
Accrued expenses	19,537	9,377
Current portion of long-term debt	<u>43</u>	<u>61</u>
Total current liabilities	36,391	29,265
Deferred revenues	55,366	38,490
Long-term debt	40,454	37,854
Other long-term liabilities	<u>1,754</u>	<u>1,923</u>
Total liabilities	133,965	107,532
Commitments and contingencies (Note 11)		
Stockholders' equity:		
Undesignated preferred stock: par value \$0.001, 5,000,000 shares authorized; no shares issued and outstanding as of December 31, 2010 and 2009	—	—
Common stock: par value \$0.001, 100,000,000 shares authorized; 54,043,317 shares issued as of December 31, 2010 and 46,795,859 shares issued and outstanding as of December 31, 2009	53	47
Additional paid-in capital	465,642	365,548
Accumulated deficit	(308,426)	(276,714)
Accumulated other comprehensive income	85	565
Treasury stock, at cost: 325,104 shares as of December 31, 2010	<u>(5,225)</u>	<u>—</u>
Total stockholders' equity	152,129	89,446
Total liabilities and stockholders' equity	<u>\$ 286,094</u>	<u>\$ 196,978</u>

See accompanying notes to these consolidated financial statements.

NXSTAGE MEDICAL, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS

	Years Ended December 31,		
	2010	2009	2008
	(In thousands, except per share data)		
Revenues	\$179,218	\$148,676	\$128,763
Cost of revenues	121,091	111,812	108,387
Gross profit	<u>58,127</u>	<u>36,864</u>	<u>20,376</u>
Operating expenses:			
Selling and marketing	34,166	30,047	27,965
Research and development	12,900	9,814	8,890
Distribution	14,751	13,918	14,267
General and administrative	<u>22,774</u>	<u>19,532</u>	<u>19,239</u>
Total operating expenses	<u>84,591</u>	<u>73,311</u>	<u>70,361</u>
Loss from operations	<u>(26,464)</u>	<u>(36,447)</u>	<u>(49,985)</u>
Other expense:			
Interest income	3	35	485
Interest expense	(4,597)	(6,522)	(3,877)
Other income (expense), net	114	(268)	4
Change in fair value of financial instruments	<u>—</u>	<u>—</u>	<u>2,536</u>
	<u>(4,480)</u>	<u>(6,755)</u>	<u>(852)</u>
Net loss before income taxes	(30,944)	(43,202)	(50,837)
Provision for income taxes	<u>768</u>	<u>265</u>	<u>374</u>
Net loss	<u>\$ (31,712)</u>	<u>\$ (43,467)</u>	<u>\$ (51,211)</u>
Net loss per share, basic and diluted	<u>\$ (0.66)</u>	<u>\$ (0.93)</u>	<u>\$ (1.23)</u>
Weighted-average shares outstanding, basic and diluted	<u>48,188</u>	<u>46,627</u>	<u>41,803</u>

See accompanying notes to these consolidated financial statements.

NXSTAGE MEDICAL, INC

CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY

	Common Stock Shares	Amount	Additional Paid-In Capital	Accumulated Deficit	Other Comprehensive Income (Loss)	Treasury Stock	Total Stockholders' Equity
Balance at December 31, 2007	36,771,893	\$37	\$311,172	\$(182,036)	\$ 544	—	\$129,717
Comprehensive loss:							
Net loss	—	—	—	—	—	—	(51,211)
Foreign currency translation adjustment	—	—	—	(51,211)	(163)	—	(163)
Total comprehensive loss	—	—	—	—	—	—	(51,374)
Issuance of common stock, net of issuance costs	9,555,556	10	37,880	—	—	—	37,890
Exercise of stock options	71,547	—	103	—	—	—	103
Shares issued under employee stock purchase and incentive plan	95,102	—	377	—	—	—	377
Shares issued to Directors in lieu of cash	54,487	—	220	—	—	—	220
Stock-based compensation expense	—	—	5,514	—	—	—	5,514
Balance at December 31, 2008	46,548,585	47	355,266	(233,247)	381	—	122,447
Comprehensive loss:							
Net loss	—	—	—	(43,467)	184	—	(43,467)
Foreign currency translation adjustment	—	—	—	—	—	—	184
Total comprehensive loss	—	—	—	—	—	—	(43,283)
Reclassification warrant liability to equity	—	—	1,858	—	—	—	1,858
Exercise of stock options	86,927	—	270	—	—	—	270
Shares issued under employee stock purchase and incentive plan	116,799	—	403	—	—	—	403
Shares issued to Directors in lieu of cash	43,548	—	196	—	—	—	196
Stock-based compensation expense	—	—	7,555	—	—	—	7,555
Balance at December 31, 2009	46,795,859	47	365,548	(276,714)	565	—	89,446
Comprehensive loss:							
Net loss	—	—	—	(31,712)	(480)	—	(31,712)
Foreign currency translation adjustment	—	—	—	—	—	—	(480)
Total comprehensive loss	—	—	—	—	—	—	(32,192)
Issuance of common stock, net of issuance costs	3,680,000	4	73,350	—	—	—	73,354
Exercise of stock options	1,831,253	1	12,034	—	—	(642)	11,393
Exercise of warrants	250,610	—	415	—	—	—	415
Shares issued under employee restricted stock and bonus plans	1,412,453	1	1,600	—	—	(4,583)	(2,982)
Shares issued under employee stock purchase plan	61,387	—	638	—	—	—	638
Shares issued to Directors in lieu of cash	11,755	—	186	—	—	—	186
Stock-based compensation expense	—	—	11,871	—	—	—	11,871
Balance at December 31, 2010	54,043,317	\$53	\$465,642	\$(308,426)	\$ 85	\$(5,225)	\$152,129

See accompanying notes to these consolidated financial statements.

NXSTAGE MEDICAL, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Years Ended December 31,		
	2010	2009	2008
	(In thousands)		
Cash flows from operating activities:			
Net loss	\$(31,712)	\$(43,467)	\$(51,211)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:			
Depreciation and amortization	22,379	20,778	19,201
Amortization of inventory step-up	—	—	52
Stock-based compensation	15,351	9,226	5,842
Change in fair value of financial instruments	—	—	(2,536)
Other	2,319	2,690	1,038
Changes in operating assets and liabilities:			
Accounts receivable	235	(2,208)	(4,761)
Inventory	(28,744)	(9,209)	(23,431)
Prepaid expenses and other assets	(877)	1,513	747
Accounts payable	(2,781)	2,568	(4,626)
Accrued expenses and other liabilities	10,065	(119)	(3,641)
Deferred revenues	16,876	5,071	10,104
Net cash provided by (used in) operating activities	3,111	(13,157)	(53,222)
Cash flows from investing activities:			
Purchases of property and equipment	(1,556)	(1,725)	(3,037)
Maturities of short-term investments	—	—	1,100
Decrease (Increase) in other assets	340	(340)	1,480
Net cash used in investing activities	(1,216)	(2,065)	(457)
Cash flows from financing activities:			
Issuance of common stock	73,354	—	42,284
Proceeds from stock option and purchase plans	12,446	673	372
Purchase of treasury stock	(4,583)	—	—
Proceeds from loans and lines of credit	—	39,895	5,000
Repayments on loans and lines of credit	(54)	(30,537)	(81)
Net cash provided by financing activities	81,163	10,031	47,575
Foreign exchange effect on cash and cash equivalents	(439)	269	(499)
Increase (decrease) in cash and cash equivalents	82,619	(4,922)	(6,603)
Cash and cash equivalents, beginning of year	21,720	26,642	33,245
Cash and cash equivalents, end of year	\$104,339	\$ 21,720	\$ 26,642
Supplemental Disclosures			
Cash paid for interest	\$ 1,628	\$ 4,749	\$ 3,308
Cash paid for taxes	\$ 365	\$ 401	\$ 641
Noncash Investing Activities			
Transfers from inventory to field equipment	\$ 20,567	\$ 10,315	\$ 21,833
Transfers from field equipment to deferred cost of revenues	\$ 21,185	\$ 7,358	\$ 12,759

See accompanying notes to these consolidated financial statements.

NXSTAGE MEDICAL, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Nature of Operations

We are a medical device company that develops, manufactures and markets innovative products for the treatment of kidney failure, fluid overload and related blood treatments and procedures. Our primary product, the NxStage System One, or System One, was designed to satisfy an unmet clinical need for a system that can deliver the therapeutic flexibility and clinical benefits associated with traditional dialysis machines in a smaller, portable, easy-to-use form that can be used by healthcare professionals and trained lay users alike in a variety of settings, including patient homes, as well as more traditional care settings such as hospitals and dialysis clinics. Given its design, the System One is particularly well-suited for home hemodialysis and a range of dialysis therapies including more frequent, or "daily," dialysis, which clinical literature suggests provides patients better clinical outcomes and improved quality of life. The System One is cleared or approved for commercial sale in the United States, Europe and Canada for the treatment of acute and chronic kidney failure and fluid overload. The System One is cleared specifically by the United States Food and Drug Administration, or FDA, for home hemodialysis as well as therapeutic plasma exchange, or TPE, in a clinical environment. We also sell needles and blood tubing sets primarily to dialysis clinics for the treatment of end-stage renal disease, or ESRD, which we refer to as the in-center market. These products are cleared or approved for commercial sale in the United States, Europe, Canada and other select markets. We believe our largest future product market opportunity is for our System One used in the home hemodialysis market, or home market, for the treatment of ESRD.

For the year ended December 31, 2010, cash flows from operating activities were positive due to improvements in net loss versus 2009 and a \$4.3 million one-time customer prepayment on first quarter 2011 orders. While we continue to make progress in improving our cash flows from operating activities, we expect cash flows from operating activities in the near term to fluctuate between negative and positive on a quarterly basis, primarily due to changes in working capital. There can be no assurance that we will be able to continue to improve cash flows from operating activities or whether we will be able to generate positive cash flows from operating activities in the future. We believe, based on current projections and the current nature of our business, that we have the required resources to fund our ongoing operating requirements. Our ability to and the rate at which we continue to improve cash flows from operating activities will depend on many factors, including growing revenues, continued improvements in gross margins, leverage of our operating infrastructure and continued sale versus rental of a significant percentage of our System One equipment.

2. Summary of Significant Accounting Policies

Principles of Consolidation and Basis of Presentation

The accompanying consolidated financial statements include the accounts of NxStage Medical, Inc. and our wholly-owned subsidiaries. All material intercompany transactions and balances have been eliminated in consolidation. Certain reclassifications have been made to prior years' financial statements to conform to the 2010 presentation.

Use of Estimates

The preparation of our consolidated financial statements in conformity with generally accepted accounting principles in the United States requires management to make estimates and assumptions that affect reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

NXSTAGE MEDICAL, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

Revenue Recognition

We recognize revenue from product sales and services when earned. Revenues are recognized when: (a) there is persuasive evidence of an arrangement, (b) the product has been shipped or services and supplies have been provided to the customer, (c) the sales price is fixed or determinable and (d) collection is reasonably assured. Our revenue arrangements with multiple elements are divided into separate units of accounting if specified criteria are met, including whether the delivered element has stand-alone value to the customer and whether there is objective and reliable evidence of the fair value of the undelivered items. The consideration received is allocated among the separate units based on their respective fair values, and the applicable revenue recognition criteria are applied to each of the separate units.

Certain agreements with distributors allow for product returns and credits. For shipment of product sold to distributors, revenue is recognized at the time of sale if a reasonable estimate of future returns or refunds can be made. If a reasonable estimate of future returns or refunds cannot be made, we recognize revenue using the "sell-through" method. Under the "sell-through" method, revenue and related costs of revenue is deferred until the final resale of such products to end customers.

In addition to contractually determined volume discounts, in many agreements we offer rebates based on sales to specific end customers and discounts for early payment. Rebates and discounts are recorded as a reduction of sales and trade accounts receivable, based on our best estimate of the amount of probable future rebate or discount on current sales.

System One Segment

We derive revenue in the home market from the sales of hemodialysis therapy to customers in which the customer either purchases or rents the System One and/or PureFlow SL hardware and purchases a specified number of disposable products and, in some instances, service.

For customers that purchase the System One and PureFlow SL hardware, we must determine whether (a) the equipment has stand-alone value and (b) the fair value of the undelivered items, typically the disposables and, in most instances service, can be determined. If either criteria is not met, which is generally the case, the arrangement is accounted for as a single unit of accounting and the fees received upon the completion of delivery of equipment are deferred and recognized as revenue on a straight-line basis over the expected term of our remaining obligation and direct costs relating to the delivered equipment are amortized over the same period as the related revenue, while disposable products revenue is recognized on a monthly basis upon delivery. If both criteria are met, then the items are accounted for separately as delivered.

Under the rental arrangements revenue is recognized on a monthly basis in accordance with agreed upon contract terms and pursuant to binding customer purchase orders and fixed payment terms.

In the critical care market, we structure sales of the System One as direct product sales and have no significant post delivery obligations with the exception of standard warrant obligations. We recognize revenue from direct product sales at the time of shipment or, if applicable, delivery in accordance with contract terms.

Our contracts for the System One in the critical care market provide for training, technical support and warranty services to our customers. We recognize training and technical support revenue when the related services are performed. In the case of extended warranty, the service revenue is recognized ratably over the warranty period.

In-Center Segment

In the In-Center segment, nearly all sales to end users are structured through supply and distribution contracts with distributors. Some of our distribution contracts for the In-Center segment contain minimum volume commitments with negotiated pricing discounts at different volume tiers. Each agreement may be

NXSTAGE MEDICAL, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

cancelled upon a material breach, subject to certain curing rights, and in many instances minimum volume commitments can be reduced or eliminated upon certain events.

Foreign Currency Translation and Transactions

Assets and liabilities of our foreign operations are translated into U.S. dollars at current exchange rates, and income and expense items are translated at average rates of exchange prevailing during the year. Gains and losses realized from transactions denominated in foreign currencies, including intercompany balances not considered permanent investments, are included in the consolidated statements of operations and totaled \$0.1 million, \$0.3 million and \$0.1 million in 2010, 2009 and 2008, respectively.

Cash, Cash Equivalents, Marketable Securities and Restricted Cash

We consider all highly-liquid investments purchased with original maturities of 90 days or less to be cash equivalents. Cash equivalents include amounts invested in federal agency securities, commercial paper and money market funds. Cash equivalents are stated at cost plus accrued interest, which approximates market value.

We had \$0.6 million of restricted cash classified as other assets at December 31, 2009 related primarily to standby letters of credit to guarantee annual VAT refunds in Italy.

Concentration of Credit Risk

Financial instruments that potentially subject us to concentrations of credit risk consist principally of cash and cash equivalents and accounts receivable. We maintain our cash in treasury obligation money market funds and bank deposit accounts which, at times, may exceed federally insured limits. We believe that the financial institutions that hold our cash are financially sound and, accordingly, minimal credit risk exists with respect to these balances.

Concentration of credit risk with respect to accounts receivable is limited to certain customers to whom we make substantial sales. One customer represented 23% of accounts receivable at December 31, 2010. One customer represented 19% of accounts receivable at December 31, 2009. To reduce risk, we routinely assess the financial strength of our customers and closely monitor their amounts due and, as a result of our assessment, believe that our accounts receivable credit risk exposure is limited. Historically, we have not experienced any significant credit losses related to an individual customer or group of customers in any particular industry or geographic area. We maintain an allowance for doubtful accounts based on an analysis of historical losses from uncollectible accounts and risks identified for specific customers who may not be able to make required payments. Provisions for the allowance for doubtful accounts are recorded in general and administrative expenses in the accompanying consolidated statements of operations.

Activity related to allowance for doubtful accounts consisted of the following (in thousands):

<u>Year Ended</u>	<u>Balance at Beginning of Year</u>	<u>Provision (Recoveries)</u>	<u>Write-offs</u>	<u>Balance at End of Year</u>
December 31, 2010	\$725	(86)	\$ (38)	\$601
December 31, 2009	\$918	—	\$(193)	\$725
December 31, 2008	\$296	\$694	\$ (72)	\$918

We use and are dependent upon a number of single source suppliers of components, subassemblies and finished goods. We are dependent on the ability of our suppliers to provide products on a timely basis and on favorable pricing terms. The loss of certain principal suppliers or a significant reduction in product availability from principal suppliers would have a material adverse effect on us, at least in the near term. We believe that our relationships with our suppliers are satisfactory.

NXSTAGE MEDICAL, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

Fair Value Measures

Certain financial and non financial assets and liabilities recorded at fair value have been classified as Level 1, 2 or 3 within the fair value hierarchy as described in the accounting standard. Fair values determined by Level 1 inputs utilize quoted prices (unadjusted) in active markets for identical assets or liabilities that we have the ability to access. Fair values determined by Level 2 inputs utilize data points that are observable such as quoted prices, interest rates and yield curves for similar instruments and model-derived valuations whose inputs are observable. Fair values determined by Level 3 inputs utilize unobservable data points for the asset or liability.

Inventory

Inventory is stated at the lower of cost, determined using the first-in first-out method (FIFO), or market (net realizable value). We record a provision for any excess or obsolete inventory when warranted based on estimated forecast of product demand and existing product configurations. We also review our inventory value to determine if it reflects the lower of cost or market based on factors such as inventory items sold at negative gross margins and purchase commitments.

Property and Equipment and Field Equipment

Property and equipment and field equipment are recorded at cost less accumulated depreciation. Depreciation is provided over the estimated useful lives of the related assets using the straight-line method for financial statement purposes. The estimated useful life of our assets are periodically reviewed for reasonableness. Changes in useful lives are accounted for prospectively. Repairs and maintenance are expensed as incurred. When property and equipment are retired, sold or otherwise disposed of, the asset's carrying amount and related accumulated depreciation are removed from the accounts and any gain or loss is included in operations. When field equipment is sold, the asset's carrying amount and related accumulated depreciation is removed from the accounts and any gain or loss is deferred and recognized in operations on a straight-line basis over the same period as the related revenues.

Construction in process is stated at cost, which includes the cost of construction and other direct costs attributable to the construction. No provision for depreciation is made on construction in process until such time as the relevant assets are completed and put into use. Construction in process at December 31, 2010 and 2009 primarily represents machinery and equipment under installation.

Field equipment consists of equipment being utilized under disposable-based rental agreements as well as "service pool" equipment. Service pool equipment is equipment owned and maintained by us that are swapped for equipment that need repairs or maintenance by us while being rented or owned by a customer. We record a provision for any excess, lost or damaged equipment when warranted based on an assessment of the number of equipment in the service pool, as well as equipment that are in-transit or otherwise not being used by a customer. Write-downs for equipment are included in distribution expenses.

The estimated useful lives of property and equipment and field equipment are as follows:

	<u>Estimated Useful Life</u>
Manufacturing equipment and tooling	5 to 6 years
Molds	4 years
Leasehold improvements	Lesser of 5 years or lease term
Computer and office equipment	3 years
Furniture	5 to 7 years
Field equipment	5 to 7 years

NXSTAGE MEDICAL, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

Intangibles and Other Long Lived Assets

Intangible assets are carried at cost less accumulated amortization. For assets with determinable useful lives, amortization is computed using the straight-line method over the estimated economic lives of the respective intangible assets, ranging from eight to fourteen years. Long-lived assets, including intangible assets, are tested for recoverability whenever events or circumstances indicate that their carrying value may not be recoverable. The amount of impairment, if any, is measured based on fair value, which is determined using estimated discounted cash flows to be generated from such assets or group of assets. During 2010, 2009 and 2008, no such impairment was recognized. Assets to be disposed of are reported at the lower of the carrying amount or fair value less selling costs.

Goodwill

Goodwill relates to amounts that arose in connection with the acquisition of Medisystems Corporation and certain affiliated entities, which we refer to collectively as Medisystems. We believe the factors contributing to the goodwill that resulted from acquiring Medisystems include (but are not limited to), increased manufacturing capacity and efficiency, securing long-term rights to certain technology and brand names and strengthening long-term customer relationships common to both Medisystems and us. We test goodwill at least annually for impairment, or more frequently when events or changes in circumstances indicate that the goodwill might be impaired. This impairment test is performed annually during the fourth quarter. Goodwill may be considered impaired if the carrying value of the reporting unit, including goodwill, exceeds the reporting unit's fair value. Reporting unit fair value is estimated using a discounted cash flow approach. During 2010, 2009 and 2008, no such impairment was recognized. Our reporting units are our System One and In-center operating segments. When testing goodwill for impairment we primarily look to the fair value of the System One segment, as a majority of the goodwill relates to the System One segment. The goodwill recognized upon acquiring Medisystems is not deductible for tax purposes.

Stock-Based Compensation

Stock-based compensation expense is estimated as of the grant date based on the fair value of the award. We use the Black-Scholes option pricing model to estimate the fair value of stock options and quoted market prices of our common stock to estimate fair value of restricted stock. The expected term is estimated using the simplified method, as defined in Staff Accounting Bulletin No. 107. The risk free interest rate for each grant is equal to the U.S. Treasury rate in effect at the time of grant for instruments with an expected life similar to the expected option term. Because of our limited trading history as a public company, the stock volatility assumption is based on an analysis of our historical volatility and the volatility of the common stock of comparable companies in the medical device and technology industries. The dividend yield of zero is based upon the fact that we have not historically granted cash dividends, and do not expect to issue dividends in the foreseeable future.

We recognize stock-based compensation expense over the requisite service period, which generally equals the vesting period, net of forfeitures. Forfeiture rates are estimated based on historical pre-vesting forfeiture history and are updated on a quarterly basis to reflect actual forfeitures of unvested awards and other known events. For awards that vest based on employment, we recognize the associated compensation expense on a straight-line basis. For performance based awards, we recognize expense using the graded vesting methodology based on the number of shares expected to vest. Compensation expense associated with these performance based awards is adjusted quarterly to reflect subsequent changes in the estimated outcome of performance-related conditions until the date the results are determined.

NXSTAGE MEDICAL, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

Warranty Costs

We accrue estimated costs that we may incur under our product warranty programs at the time the product revenue is recognized, based on contractual rights and historical experience. Warranty expense is included in cost of revenues in the consolidated statements of operations. The following is a rollforward of our warranty accrual (in thousands):

<u>Year Ended</u>	<u>Balance at Beginning of Year</u>	<u>Provision</u>	<u>Usage</u>	<u>Balance at End of Year</u>
December 31, 2010	\$205	\$452	\$(389)	\$268
December 31, 2009	\$235	\$331	\$(361)	\$205
December 31, 2008	\$220	\$366	\$(351)	\$235

Distribution Expenses

Distribution expenses are charged to operations as incurred and consist of costs incurred in shipping product to and from customers and the cost of any equipment lost or damaged in the distribution process. Shipping and handling costs billed to customers are included in revenues and totaled \$0.3 million in 2010 and \$0.2 million in both 2009 and 2008.

Research and Development Costs

Research and development costs are charged to operations as incurred.

Income Taxes

We record the tax effect of transactions when such transactions are recorded in our consolidated statement of operations. We record a deferred tax asset or liability based on the difference between the financial statement and tax basis of assets and liabilities, as measured by the enacted tax rates. Our provision for income taxes represents the amount of taxes currently payable, if any, plus the change in the amount of net deferred tax assets or liabilities. A valuation allowance is provided against net deferred tax assets if recoverability is uncertain on a more likely than not basis.

We periodically assess our exposures related to our provisions for income taxes and accrue for contingencies that may result in potential tax obligations. For those positions where it is more likely than not that a tax benefit will be sustained, we record the largest amount of tax benefit with a greater than 50 percent likelihood of being realized upon ultimate settlement with a taxing authority that has full knowledge of all relevant information. For those income tax positions where it is not more likely than not that a tax benefit will not be sustained, no tax benefit is recognized in the financial statements. We recognize interest and penalties for uncertain tax positions in income tax expense.

We file federal, state and foreign tax returns. We have accumulated significant losses since our inception in 1998. Since the net operating losses may potentially be utilized in future years to reduce taxable income, all of our tax years remain open to examination by the major taxing jurisdictions to which we are subject.

Comprehensive Loss

We have chosen to disclose comprehensive loss, which consists of net loss and other comprehensive income (loss), in the consolidated statement of changes in stockholders' equity. Other comprehensive income (loss) primarily includes foreign currency translation adjustments that are excluded from results of operations.

NXSTAGE MEDICAL, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

Subsequent Events

Events occurring subsequent to December 31, 2010 have been evaluated for potential recognition or disclosure in the consolidated financial statements.

Recent Accounting Pronouncements

Effective January 1, 2010, we adopted an accounting standard update regarding accounting for transfers of financial assets. As codified under Accounting Standards Codification, or ASC 860, this update prescribes the information that a reporting entity must provide in its financial reports about a transfer of financial assets; the effects of a transfer on its financial position, financial performance, and cash flows; and a transferor's continuing involvement in transferred financial assets. Specifically, among other aspects, the update amends Statement of Financial Accounting Standards No. 140, *Accounting for Transfers and Servicing of Financial Assets and Extinguishments of Liabilities*, or SFAS 140, by removing the concept of a qualifying special-purpose entity from SFAS 140 and removes the exception from applying FASB Interpretation No. 46, *Consolidation of Variable Interest Entities (revised)*, to variable interest entities that are qualifying special-purpose entities. It also modifies the financial-components approach used in SFAS 140. Because the update is effective for transfers of financial assets occurring on or after January 1, 2010 and we have not had any such transactions subsequent to January 1, 2010 to date, the adoption of this update did not have an impact on our consolidated financial statements.

Effective January 1, 2010, we adopted an accounting standard update regarding fair value measurements. As codified under ASC 820, this update requires additional disclosures about fair value measurements including transfers in and out of Levels 1 and 2 and a higher level of disaggregation for the different types of financial instruments. For the reconciliation of Level 3 fair value measurements, information about purchases, sales, issuances and settlements should be presented separately. Because this update addresses disclosure requirements, the adoption of this update did not impact our financial position, results of operations or cash flows.

In September 2009, the FASB issued two new Accounting Standard Updates, or ASUs, affecting revenue recognition: ASU No. 2009-13, *Multiple-Deliverable Revenue Arrangements*, and ASU No. 2009-14, *Certain Revenue Arrangements That Include Software Elements*. The revised guidance primarily provides two significant changes to the previous guidance for multiple-deliverable revenue recognition arrangements. First, it eliminates the need for objective and reliable evidence of the fair value for the undelivered element in order for a delivered item to be treated as a separate unit of accounting. Second, it eliminates the residual method to allocate the arrangement consideration. In addition, the guidance also expands the disclosure requirements for revenue recognition. We adopted these ASUs effective January 1, 2011, as required, using the prospective method as permitted under the guidance. Accordingly, this guidance will be applied to all revenue arrangements entered into or materially modified on or after January 1, 2011. Based upon our evaluation of the new guidance, the impact of adopting this new guidance on our results of operations will be limited to products sold internationally through distributors in the System One segment, which revenue has not been significant in the historical periods. Additionally, the adoption of these ASUs will result in expanded disclosures around revenue recognition.

3. Significant Revenue Contracts

National Service Provider Agreement with DaVita Inc., or DaVita

In February 2007, we entered into a National Service Provider Agreement, or the Original Agreement with DaVita, a significant customer, in which we agreed to sell the System One and PureFlow SL hardware along with the right to purchase disposable products and service on a monthly basis. The Original Agreement included other terms such as development efforts, training, market collaborations and volume discounts. The

NXSTAGE MEDICAL, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

Original Agreement expired on December 31, 2009, but sales continued in accordance with the terms specified in the Original Agreement.

In July 2010, we entered into a First Amended and Restated National Service Provider Agreement, or the Amended Agreement, with DaVita which supersedes the Original Agreement. Pursuant to the terms of the Amended Agreement, we will continue to sell the System One and PureFlow SL hardware along with the right to purchase disposable products and service on a monthly basis. The Amended Agreement includes other terms such as rebates, training and volume discounts.

The sale of equipment and other items included in the Original Agreement and the Amended Agreements were considered to be multiple-element sales arrangements pursuant to ASC 605, *Revenue Recognition*. We have determined that we cannot account for the sale of equipment as a separate unit of accounting. Therefore, fees received upon the completion of delivery of equipment under the Original and Amended Agreements are deferred and recognized as revenues on a straight-line basis over the expected term of our obligation to supply disposables and service, which is seven years, and direct costs relating to the delivered equipment are deferred and amortized over the same period as the related revenues.

In connection with the Amended Agreement we issued to DaVita a warrant that may vest and become exercisable to purchase up to 5.5 million shares of our common stock based upon the achievement of certain DaVita and NxStage System One home patient growth targets on separate measurement dates occurring on June 30, 2011, 2012 and 2013. The warrants have an exercise price of \$14.22 per share, are non-transferable, must be exercised in cash and, if vested, expire during 2013. The warrants will be measured at fair value through their date of vesting using the Black-Scholes option pricing model, and recognized as a reduction of revenues, based on the number of warrants expected to vest, over the same period as the related product revenues which is 7 to 10 years. Estimates of the number of warrants expected to vest and the fair value of the warrants will be revised each reporting period through the date of vesting. The reduction of revenues recorded in connection with these warrants was not significant during 2010.

Asahi Strategic Business Alliance

In May 2009, we entered into a series of agreements with Asahi Kasei Kuraray Medical, or Asahi, a leading medical supply company headquartered in Japan which we consider to be a single arrangement. The agreements are multi-faceted and include a Term Loan and Security Agreement, or Loan Agreement, and a Technology and Trademark License Agreement, or License Agreement.

Under the terms of the Loan Agreement, Asahi agreed to provide us with \$40.0 million of debt financing. The four year loan bears interest at 8% annually, with 50% of the interest deferred to maturity in May 2013. We estimated the fair value of the loan at issuance using quoted prices for similar debt instruments, level 2 measurements within the fair value hierarchy. The fair value of the loan of \$36.3 million was recorded in our consolidated financial statements, net of a \$3.7 million discount. The discount will be amortized ratably over the term of the loan into interest expense. In accordance with the terms of the License Agreement, we granted Asahi a royalty-free license to our Streamline blood tubing set technology and production technology to make and sell our current dialyzer design. We estimated the fair value of the license using an income approach, namely the relief from royalty approach, which requires assumptions related to future cash flows, assumed royalty rates and a discount rate, level 3 measurements within the fair value hierarchy. The fair value of the license of \$3.7 million was recorded as deferred revenue and will be recognized as revenue over the estimated life of the underlying patents, of six to seven years. The deferral of the consideration allocated to the license represents a noncash operating activity.

NXSTAGE MEDICAL, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

System One Segment Distribution Arrangements

In 2009, we began entering into arrangements with distributors to sell the System One equipment and related disposables and certain of our other products internationally. The arrangements typically have a term of five years and may be terminated upon material breach by either party.

The sale of equipment and other items included in these arrangements were considered to be multiple-element sales arrangements pursuant to ASC 605, *Revenue Recognition*. We have determined that we cannot account for the sale of equipment as a separate unit of accounting. Therefore, fees received upon the completion of delivery of equipment under these arrangements are deferred and recognized as revenues on a straight-line basis over the longer of the economic life of the equipment or the expected term of our obligation to supply disposables pursuant to the agreement, which is typically five years. We have deferred both the unrecognized revenues and direct costs relating to the delivered equipment, which costs are being amortized over the same period as the related revenues. However, effective January 1, 2011 we adopted two new Accounting Standard Updates, or ASUs, which will affect revenue recognition for sales to our international distributors. Under the amended guidance, beginning January 1, 2011, we will recognize revenues from equipment sale and related direct costs at the time of shipment or, if applicable, delivery in accordance with contract terms. The adoption of this amended guidance will not impact the accounting for sales prior to January 1, 2011. We will continue to recognize revenues from these equipment sales ratably.

4. Inventory

Inventory includes material, labor and overhead. The components of inventory are as follows (in thousands):

	December 31, 2010	December 31, 2009
Purchased components	\$14,928	\$10,110
Work in process	6,372	5,744
Finished goods	13,650	12,263
	\$34,950	\$28,117

5. Property and Equipment, Field Equipment and Deferred Cost of Revenues

A summary of the components of property and equipment, net are as follows (in thousands):

	December 31, 2010	December 31, 2009
Manufacturing equipment and tooling	\$ 10,683	\$ 9,804
Leasehold improvements	3,913	4,846
Computer and office equipment	2,272	2,283
Molds	1,848	1,803
Furniture	238	471
Construction-in-process	1,179	1,619
	20,133	20,826
Less accumulated depreciation	(11,843)	(10,490)
Property and equipment, net	\$ 8,290	\$ 10,336

Depreciation expense for property and equipment was \$3.3 million, \$3.4 million and \$3.0 million for the years ended December 31, 2010, 2009 and 2008, respectively.

NXSTAGE MEDICAL, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

The components of field equipment, net are as follows (in thousands):

	<u>December 31, 2010</u>	<u>December 31, 2009</u>
Field equipment	\$ 42,753	\$ 48,381
Less accumulated depreciation	<u>(29,093)</u>	<u>(26,655)</u>
Field equipment, net	<u>\$ 13,660</u>	<u>\$ 21,726</u>

Depreciation expense for field equipment, which is recorded in costs of revenues in the consolidated statement of operations, was \$8.1 million, \$9.8 million and \$9.0 million for the years ended December 31, 2010, 2009 and 2008, respectively.

Amortization expense of deferred cost of revenues was \$8.1 million, \$4.6 million and \$3.5 million for the years ended December 31, 2010, 2009 and 2008, respectively.

6. Goodwill and Intangible Assets

Intangible assets consisted of the following (in thousands):

	<u>December 31, 2010</u>		<u>December 31, 2009</u>		<u>Estimated Useful Life</u>
	<u>Cost</u>	<u>Accumulated Amortization</u>	<u>Cost</u>	<u>Accumulated Amortization</u>	
Bloodline, needle and other patented and unpatented technology	\$ 6,200	\$(2,519)	\$ 6,200	\$(1,744)	8 years
Trade names	2,300	(534)	2,300	(370)	14 years
Customer relationships	<u>26,000</u>	<u>(6,035)</u>	<u>26,000</u>	<u>(4,178)</u>	14 years
Intangible assets	<u>\$34,500</u>	<u>\$(9,088)</u>	<u>\$34,500</u>	<u>\$(6,292)</u>	

We recognized amortization expense of \$2.8 million during each of 2010, 2009 and 2008. We will record \$2.8 million of amortization expense for each of the years ending December 31, 2011 through 2015 and \$11.4 million in the aggregate thereafter related to the above intangible assets.

7. Net Loss per Share

Basic loss per share is computed by dividing loss available to common stockholders (the numerator) by the weighted-average number of common shares outstanding (the denominator) for the period. The computation of diluted loss per share is similar to basic loss per share, except that the denominator is increased to include the number of additional common shares that would have been outstanding if the potentially dilutive common shares had been issued.

The following potential common stock equivalents, as calculated using the treasury stock method, were not included in the computation of diluted net loss per share as their effect would have been anti-dilutive due to the net loss incurred (in thousands):

	<u>Years Ended December 31,</u>		
	<u>2010</u>	<u>2009</u>	<u>2008</u>
Options to purchase common stock	3,072	584	275
Restricted stock	913	888	—
Warrants to purchase common stock	<u>989</u>	<u>—</u>	<u>—</u>
Total	<u>4,974</u>	<u>1,472</u>	<u>275</u>

NXSTAGE MEDICAL, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

8. Accrued Expenses

Accrued expenses consist of the following (in thousands):

	December 31, 2010	December 31, 2009
Payroll, compensation and related benefits	\$ 7,109	\$4,433
Customer prepayment	4,316	—
Distribution expenses	2,228	1,616
Other	5,884	3,328
Total	<u>\$19,537</u>	<u>\$9,377</u>

9. Debt

In November 2007, we obtained a \$50.0 million credit and security agreement with a term of 42 months from a group of lenders led by Merrill Lynch Capital, a division of Merrill Lynch Business Services Inc., which was subsequently acquired by General Electric Capital, or GE. The credit facility consisted of a \$30.0 million term loan and a \$20.0 million revolving credit facility. On March 16, 2009, the Company amended its credit and security agreement with GE. The amendment postponed principal payments under the term loan for three months from April through June 2009, and modified certain covenants and the interest rate on the term loan and revolving credit facility. Interest on the amended term loan was 11.12% per annum payable on a monthly basis. We were also required to pay a maturity premium of \$0.9 million at the time of loan payoff. We accrued the maturity premium as additional interest over the term. The revolving credit facility of the loan included an unused line fee of 0.75% per annum and descending deferred revolving credit facility commitment fees, which would be charged in the event the revolving credit facility was terminated prior to May 21, 2011. We paid a \$0.5 million amendment fee in connection with the March 2009 amendment. Concurrent with entering into the term loan with Asahi in June 2009, we terminated the GE credit and security agreement and repaid all outstanding borrowings owed, including \$2.0 million of prepayment and other transactions fees which were recorded to interest expense during 2009.

In June 2009, we closed a \$40.0 million term loan and security agreement with Asahi. Borrowings bear interest at a rate of 8% per annum payable in arrears on November 1st and May 1st, with fifty percent of such interest being deferred until the maturity date on May 31, 2013. Principal is payable in one balloon payment at maturity. The term loan is secured by substantially all of our assets. The term loan may be prepaid, without penalty, at our option. In the event the term loan reaches maturity, Asahi may require that all of the principal and interest on the term loan that is unpaid as of the maturity date be converted into shares of our common stock, with the number of shares to be determined based upon the average closing stock price of our common stock during the thirty business days preceding the maturity date. Under no circumstance would we be obligated to issue more than 10% of the number of our shares of common stock outstanding on the maturity date to Asahi in satisfaction of this obligation; provided that we and Asahi may mutually agree, in each of our own sole discretion, to increase the 10% limitation up to 20%. The term loan and security agreement with Asahi includes certain affirmative covenants including timely filings and limitations on contingent debt obligations and sales of assets. The term loan and security agreement also contains customary events of default, including nonpayment, misrepresentation, breach of covenants, material adverse effects, and bankruptcy. In the event we fail to satisfy the covenants, or otherwise go into default, Asahi has a number of remedies, including sale of our assets and acceleration of all outstanding indebtedness, subject to SVB's senior security interest. Borrowings under the term loan and security agreement were recorded at their estimated fair value at issuance, net of a \$3.7 million discount. The discount is being recorded to interest expense over the term of the agreement, through May 31, 2013.

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In March 2010, we entered into a loan and security agreement with Silicon Valley Bank, or the SVB Agreement, for a \$15.0 million revolving line of credit with a maturity date of April 1, 2012. The SVB Agreement is secured by all or substantially all of our assets. In connection with the SVB Agreement, we amended the term loan and security agreement with Asahi to provide for certain amendments, including granting to Asahi junior liens on certain of our assets for so long as the SVB Agreement remains outstanding. Upon termination of all obligations under that facility, Asahi's security will revert to a security in all assets other than cash, bank accounts, accounts receivable, field equipment and inventory. Borrowings under the SVB Agreement bear interest at a floating rate per annum equal to two percentage points (2.00%) above the prime rate (initial prime rate of 4.00%). Pursuant to the SVB Agreement, we have agreed to certain financial covenants relating to liquidity requirements and adjusted EBITDA, as defined in the SVB Agreement. The SVB Agreement contains events of default customary for transactions of this type, including nonpayment, misrepresentation, breach of covenants, material adverse effect and bankruptcy. We have not drawn any amounts under the SVB Agreement and, at December 31, 2010, we were in compliance with the covenants.

In addition to the \$40.0 million term loan, we have one Euro denominated loan outstanding of \$43 thousand, which expires in September 2011, and is included in current liabilities.

Annual maturities of principal under our debt obligations outstanding at December 31, 2010, gross of a \$2.2 million discount, are as follows (in thousands):

2011	\$	43
2012		—
2013(1)		<u>42,667</u>
		<u>\$42,710</u>

(1) Amount includes \$2.7 million of deferred interest related to the Asahi term loan.

10. Business Segment and Geographic Information

After an evaluation of the business activities regularly reviewed by our chief operating decision-maker for which separate discrete financial information is available, we determined that we have two reporting segments, System One and In-Center. Beginning in the first quarter of 2009, we allocated previously unallocated cost of revenues to our System One and In-Center segments. Prior year segment information has been revised to conform to the current presentation.

The accounting policies of the reportable segments are the same as those described in Note 2, "Summary of Significant Accounting Policies." The profitability measure employed by us and our chief operating decision maker for making decisions about allocating resources to segments and assessing segment performance is segment (loss) profit, which consists of sales, less cost of sales, selling and marketing and distribution expenses.

Our management measures are designed to assess performance of these operating segments excluding certain items. As a result, certain corporate expenses are excluded from the segment operating performance measures, including research and development expenses and general and administrative expenses, as they are managed centrally.

Within the System One segment, we derive revenues from the sale and rental of the System One and PureFlow SL equipment and the sale of disposable products in the home and critical care markets. The home market is devoted to the treatment of ESRD patients in the home, while the critical care market is devoted to the treatment of hospital-based patients with acute kidney failure or fluid overload. Within the System One segment, we sell a similar technology platform of the System One with different features to the home and critical care markets. Some of our largest customers in the home market provide outsourced renal dialysis

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services to some of our customers in the critical care market. Sales of product to both markets are made primarily through dedicated sales forces and distributed directly to the customer, or the patient, with certain products sold through distributors internationally.

Within the In-Center segment, we sell blood tubing sets and needles for hemodialysis and needles for apheresis primarily for the treatment of ESRD patients at dialysis centers. Nearly all In-Center products are sold through national distributors.

Our reportable segments consist of the following (in thousands):

	<u>System One</u>	<u>In-Center</u>	<u>Unallocated</u>	<u>Total</u>
Year Ended December 31, 2010				
Revenues from external customers	\$113,855	\$65,363	\$ —	\$179,218
Segment profit (loss)	283	8,927	(35,674)	(26,464)
Segment assets	86,469	16,329	183,296	286,094
Year Ended December 31, 2009				
Revenues from external customers	\$ 85,801	\$62,875	\$ —	\$148,676
Segment (loss) profit	(17,445)	10,344	(29,346)	(36,447)
Segment assets	74,534	17,346	105,098	196,978
Year Ended December 31, 2008				
Revenues from external customers	\$ 66,873	\$61,890	\$ —	\$128,763
Segment (loss) profit	(23,092)	10,075	(36,968)	(49,985)

Substantially all of our revenues are derived from the sale of the System One and related products, which cannot be used with any other dialysis system, and from needles and blood tubing sets to customers located in the United States.

The following table summarizes the number of customers who individually comprise greater than 10% of total revenues:

	<u>Years Ended</u> <u>December 31,</u>		
	<u>2010</u>	<u>2009</u>	<u>2008</u>
Customer A	22%	22%	18%
Customer B	16%	28%	39%
Customer C	13%	—	—

Sales to Customer A are primarily in the System One segment and sales to Customer B and Customer C are to significant distributors in the In-Center segment. A portion of Customer B's sales of our products are to customer A. All of Customer C's sales of our products are to Customer A.

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

The following table presents a reconciliation of the total segment assets to total assets (in thousands):

	December 31, 2010	December 31, 2009
Total segment assets	\$102,798	\$ 91,880
Corporate assets:		
Cash and cash equivalents	104,339	21,720
Property and equipment, net	8,290	10,336
Intangible assets, net	25,412	28,208
Goodwill	42,698	42,698
Prepaid and other assets	2,557	2,136
Total assets	\$286,094	\$196,978

Long-lived tangible assets consist of property and equipment and field equipment. The following table presents total long-lived tangible assets by geographic area (in thousands):

	December 31, 2010	December 31, 2009	December 31, 2008
United States	\$16,796	\$25,922	\$35,924
Europe	4,536	5,290	5,679
Mexico	618	850	1,096
	\$21,950	\$32,062	\$42,699

11. Commitments and Contingencies

We enter into arrangements to purchase inventory requiring minimum purchase commitments in the ordinary course of business.

In connection with the October 1, 2007 acquisition of Medisystems, we assumed a supply and distribution agreement with Kawasumi, a Japanese contract manufacturer, which we refer to as the Original Agreement. The Original Agreement originally covered both blood tubing sets and needles for the In-Center segment. On May 6, 2008, we entered into a new supply and distribution agreement with Kawasumi, or the New Agreement, which supersedes the Original Agreement with respect to the supply of blood tubing sets. The Original Agreement continues to govern the purchase and sale of needles. The initial term of the New Agreement was extended through January 2012. Pursuant to the New Agreement, Kawasumi agreed not to sell blood tubing sets to any other entity in the United States and we agreed to purchase certain annual minimum quantities of blood tubing sets. The initial term of the Original Agreement was recently automatically extended through February 2014. Pursuant to the Original Agreement, we agreed to purchase certain annual minimum quantities of needles.

On March 1, 2007, we entered into a long-term agreement with the Entrada Group, or Entrada, to establish manufacturing and service operations in Mexico, initially for our cyclor and PureFlow SL disposables and later for our PureFlow SL hardware. The agreement obligates Entrada to provide us with manufacturing space, support services and a labor force through 2012. Subject to certain exceptions, we are obligated for facility fees through the term of the agreement which approximate \$0.2 million annually. The agreement may be terminated by either party upon material breach, generally following a 30-day cure period, or upon the insolvency of the other party.

In January 2007, we entered into a long-term supply agreement with Membrana, pursuant to which Membrana has agreed to supply, on an exclusive basis, capillary membranes for use in the filters used with

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

the System One for ten years. In exchange for Membrana's agreement to pricing reductions based on volumes ordered, we have agreed to purchase a base amount of membranes per year from Membrana. The agreement may be terminated by either party upon a material breach, generally following a 60-day cure period, or upon the insolvency of the other party.

We maintain our corporate headquarters in a leased building located in Lawrence, Massachusetts and maintain our manufacturing operations in Mexico, Germany, and Italy. Our lease agreement at our headquarters expires in July 2012 with an option to renew for five years. Our leased manufacturing facilities are subject to lease agreements with termination dates beginning in 2011. The lease agreements contain certain provisions that require us to pay executory costs such as real estate taxes, operating expenses and common utilities. The total amount of rental payments due over the lease term is being charged to rent expense on the straight-line method over the term of the lease. Rent expense, net of sublease income, was \$1.7 million for both the years ended December 31, 2010 and 2009 and \$1.8 million for the year ended December 31, 2008. The lease agreement for our headquarters included a tenant improvement allowance paid by the landlord of \$0.6 million, which has been recorded as both a leasehold improvement and a deferred rent obligation. All of our leases are accounted for as operating leases.

The future minimum rental payments as of December 31, 2010 under our operating leases are as follows (in thousands):

2011	\$1,578
2012	551
2013	<u>5</u>
	<u>\$2,134</u>

12. Income Taxes

Deferred income tax assets and liabilities reflect the tax effects of differences in the recognition of income and expense items for tax and financial reporting purposes.

Deferred tax assets (liabilities), the majority of which are non-current, are comprised of the following (in thousands):

	<u>December 31, 2010</u>	<u>December 31, 2009</u>
Deferred tax assets:		
Net operating loss carryforwards	\$ 105,578	\$ 95,610
Research and development credits	6,438	5,271
Other	<u>5,495</u>	<u>6,843</u>
Total deferred tax assets	<u>117,511</u>	<u>107,724</u>
Deferred tax liabilities:		
Depreciation	(2,432)	(4,938)
Intangible assets	<u>(9,707)</u>	<u>(11,048)</u>
Total deferred tax liabilities	(12,139)	(15,986)
Net deferred tax assets before valuation allowance	105,372	91,738
Less: Valuation allowance	<u>(105,372)</u>	<u>(91,738)</u>
Net deferred tax assets	<u>\$ —</u>	<u>\$ —</u>

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As of December 31, 2010, we had federal and state net operating loss carryforwards of approximately \$280 million and \$244 million, respectively, available to offset future taxable income, if any. Substantially all net losses are in the United States. The federal and state net operating loss carryforwards will expire between 2019 and 2030 if not utilized. We also had federal and state research and development credit carryforwards of \$4.4 million and \$4.3 million, which begin to expire in 2015 if not utilized. During 2010, the deferred tax valuation allowance increased by approximately \$13.6 million, primarily as the result of increases to net operating losses. A full valuation allowance has been recorded in the accompanying consolidated financial statements to offset our deferred tax assets because the future realizability of such assets is uncertain. Utilization of the net operating loss carryforwards may be subject to annual limitations due to the ownership percentage change limitations provided by the Internal Revenue Code Section 382 and similar state provisions. In the event of a deemed change in control under Internal Revenue Code Section 382, an annual limitation imposed on the utilization of net operating losses may result in the expiration of all or a portion of the net operating loss carryforwards.

The deferred tax assets above exclude deductions related to the exercise of stock options subsequent to the adoption of the guidance related to share-based payments. We will realize the benefit of these losses through increases to stockholders' equity in future periods when and if the losses are utilized to reduce future tax payments.

The provision for income taxes of \$0.8 million, \$0.3 million and \$0.4 million in 2010, 2009 and 2008, respectively, relates primarily to the profitable operations of certain foreign entities.

A reconciliation of the U.S. federal statutory tax rate to the effective tax rate is as follows:

	<u>Years Ended December 31,</u>		
	<u>2010</u>	<u>2009</u>	<u>2008</u>
Federal statutory rate	34.0%	34.0%	34.0%
Stock compensation	9.2%	(2.6)%	(2.3)%
State income tax, net of federal tax benefit	5.3%	4.9%	0.0%
Valuation allowance	(53.0)%	(38.5)%	(34.2)%
Other, net	<u>2.0%</u>	<u>1.6%</u>	<u>1.8%</u>
Effective tax rate	<u>(2.5)%</u>	<u>(0.6)%</u>	<u>(0.7)%</u>

We had unrecognized tax benefits of \$0.5 million and \$0.1 million at December 31, 2010 and 2009, respectively that would, if recognized, affect our effective tax rate. We do not anticipate a significant change in the amount of these unrecognized tax benefits over the next twelve months. Since we are in a loss carryforward position, we are generally subject to US federal, state, local and foreign income tax examinations by tax authorities for all years for which a loss carryforward is available.

13. Stock Plans and Stock-Based Compensation

Stock Incentive Plans

We maintain the 2005 Stock Incentive Plan, or the 2005 Plan, that governs awards to both employees and non-employees. The 2005 Plan replaced and superseded our 1999 Stock Option and Grant Plan, or the 1999 Plan, except that awards granted under the 1999 Plan remain in effect pursuant to their original terms. Pursuant to an amendment to the 2005 Plan approved by our shareholders in May 2009, each share award issued after May 28, 2009 other than options or stock appreciation rights will reduce the number of total shares available for grant by 1.23 shares. A total of 9.5 million shares have been authorized for grant under the 2005 Plan and, at December 31, 2010, 316,915 shares are available for future grant.

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Unless otherwise specified by our Board of Directors or Compensation Committee of the Board, stock options issued to employees under the 2005 Plan expire seven years from the date of grant and generally vest over a period of four years. In general, all stock options issued under the 1999 Plan expire ten years from the date of grant and the majority of these awards granted under the 1999 Plan were exercisable upon the date of grant into restricted common stock, which vested over a period of four years. Stock option grants to directors expire five years from the date of grant and vest 100% on date of grant. We settle stock option exercises and restricted stock vesting with newly issued common shares.

We also maintain a performance based restricted stock plan, or the Performance Share Plan, in which we commit to grant shares of restricted stock to certain employees and executive officers based on the achievement of certain annual corporate financial performance metrics. The restricted stock, if awarded, vests over a requisite service period of three years. Further, we maintain a bonus plan, or Corporate Bonus Plan, for the benefit of our employees. Payout under the Corporate Bonus Plan is based on individual performance and the achievement of certain annual corporate financial performance metrics and is paid in shares of our common stock, or in cash, at the discretion of the Compensation Committee. The estimated payout under the Corporate Bonus Plan is recognized as compensation expense during the performance year and is classified as a liability, until settlement, on our consolidated balance sheet. A significant majority of the compensation expense associated with the Corporate Bonus Plans for the 2010 and 2009 performance years has been classified as stock-based compensation expense because these amounts have been or will be paid in shares of our common stock.

Our 2005 Employee Stock Purchase Plan, or the 2005 Purchase Plan, authorized the issuance of up to 650,000 shares of common stock to participating employees through a series of periodic offerings. Each six-month offering period begins in January and July. An employee becomes eligible to participate in the 2005 Purchase Plan once he or she has been employed for at least three months and is regularly employed for at least 20 hours per week for more than three months in a calendar year. The price at which employees can purchase common stock in an offering is 95 percent of the closing price of our common stock on the NASDAQ Global Select Market on the lower of the first or last day of the offering period, unless otherwise determined by the Board or Compensation Committee. As of December 31, 2010, the maximum number of shares available for future issuance under the 2005 Purchase Plan is 335,101.

Stock Options

A summary of the status of stock options granted under all of our plans at December 31, 2010, and changes during the year then ended, is as follows:

<u>Stock Options</u>	<u>Shares</u>	<u>Weighted Average Exercise Price</u>	<u>Aggregate Intrinsic Value</u> (In thousands)	<u>Average Remaining Contractual Life</u> (In years)
Outstanding at beginning of year	6,850,050	\$ 6.87		
Granted	1,398,300	\$10.86		
Exercised	(1,831,253)	\$ 6.57		
Forfeited or expired	<u>(194,135)</u>	<u>\$10.85</u>		
Outstanding at end of year	<u>6,222,962</u>	<u>\$ 7.75</u>	\$106,578	4.26
Fully vested and exercisable	<u>3,709,004</u>	<u>\$ 7.76</u>	\$ 63,507	3.51
Fully vested, exercisable and expected to vest	<u>6,015,966</u>	<u>\$ 7.75</u>	\$103,073	4.22

The intrinsic value for stock options is calculated based on the market price of our common stock as of December 31, 2010, less the exercise price of the underlying awards, excluding out-of-the-money awards. The

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NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

total fair value of options that vested during the years ended December 31, 2010, 2009 and 2008 was \$6.6 million, \$6.0 million and \$5.7 million, respectively. The aggregate intrinsic value of options exercised is calculated based on the market price of our common stock on the exercise date, less the exercise price of underlying award and was \$21.7 million, \$0.3 million and \$0.2 million for the years ended December 31, 2010, 2009 and 2008, respectively.

The weighted-average fair value of options granted during the years ended December 31, 2010, 2009 and 2008 was \$5.84, \$1.33 and \$2.85 per option, respectively. The fair value of options at date of grant was estimated using the Black-Scholes option-pricing model with the following assumptions:

	Years Ended December 31,		
	2010	2009	2008
Expected life (in years)	4.75	4.75	4.75
Risk-free interest rate	1.17% - 2.58%	1.71% - 2.58%	2.40% - 3.70%
Expected stock price volatility	64% to 65%	65% to 75%	67%
Expected dividend yield	—	—	—

Restricted Stock

The total fair value of restricted stock that vested was \$1.8 million during the year ended December 31, 2010 and \$0.1 million during each of the years ended December 31, 2009 and 2008. The weighted-average fair value of restricted stock granted during the years ended December 31, 2010, 2009 and 2008 was \$10.00, \$2.11 and \$14.98 per unit, respectively. The following table summarizes the status of the unvested restricted stock:

	Shares	Weighted Average Grant-date Fair Value	Aggregate Intrinsic Value (In thousands)	Weighted Average Remaining Contractual Life (In years)
Nonvested at December 31, 2009	1,226,564	\$ 2.23		
Granted	757,144	\$10.00		
Vested	(804,075)	\$ 2.22		
Forfeited	<u>(26,250)</u>	<u>\$ 2.11</u>		
Nonvested at December 31, 2010	<u>1,153,383</u>	<u>\$ 7.34</u>	<u>\$28,696</u>	5.8

Employee Stock Purchase Plan

The weighted-average fair value of stock purchase rights granted as part of the 2005 Purchase Plan during the years ended December 31, 2010, 2009 and 2008 was \$2.72, \$0.97 and \$0.87 per share, respectively. The fair value of the employees' stock purchase rights was estimated using the Black-Scholes option-pricing model with the following assumptions:

	Years Ended December 31,		
	2010	2009	2008
Expected life (in months)	6	6	6
Risk-free interest rate	0.20% - 0.22%	0.18% - 0.33%	1.6% - 3.4%
Expected stock price volatility	64%	65%	65% - 67%
Expected dividend yield	—	—	—

There were 61,387, 103,551 and 85,691 shares issued under the 2005 Purchase Plan for the years ended December 31, 2010, 2009 and 2008, respectively, which resulted in share-based compensation expense of

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\$0.2 million for the year ended December 31, 2010 and \$0.1 million for each of the years ended December 31, 2009 and 2008.

Stock-based Compensation Expense

The following table presents stock-based compensation expense included in the consolidated statements of operations (in thousands):

	<u>Years Ended December 31,</u>		
	<u>2010</u>	<u>2009</u>	<u>2008</u>
Cost of revenues	\$ 2,347	\$1,593	-\$1,053
Selling and marketing	5,540	3,507	2,247
Research and development	2,222	774	520
General and administrative	<u>5,242</u>	<u>3,352</u>	<u>2,022</u>
Total stock-based compensation expense	<u>\$15,351</u>	<u>\$9,226</u>	<u>\$5,842</u>

As of December 31, 2010, approximately \$14.0 million of unrecognized stock compensation cost related to nonvested stock options and restricted stock (net of estimated forfeitures) is expected to be recognized over a weighted-average period of 2.0 years.

Other Compensation Plans

We maintain postemployment benefit plans for employees in certain foreign subsidiaries. The plans provide lump sum benefits, payable based on statutory regulations for voluntary or involuntary termination. Where required, we obtain an annual actuarial valuation of the benefit plans. We have recorded a liability of \$1.5 million and \$1.6 million at December 31, 2010 and 2009, respectively, as other long-term liabilities for costs associated with these plans. The expense recorded in connection with these plans was not significant during 2010, 2009 and 2008.

14. Employee Benefit Plan

We have a 401(k) retirement plan, or the 401(k) Plan, for the benefit of eligible employees, as defined. Each participant may elect to contribute up to 25% of his or her compensation to the 401(k) Plan each year, subject to certain IRS limitations. We contribute 100% of the first 3% of the employee's contribution and 50% of the next 2% of the employee's contribution. We contributed \$1.0 million, \$1.0 million and \$0.9 million to the 401(k) Plan during the years ended December 31, 2010, 2009 and 2008, respectively.

15. Stockholders' Equity

In November 2010, we filed an automatic shelf registration statement on Form S-3, which will allow us to offer and sell, from time to time in one or more offerings common or preferred stock, debt securities or warrants for the purchase of common or preferred stock as we deem prudent or necessary to raise capital at a later date. On November 23, 2010, we completed the sale of 3,680,000 shares of our common stock pursuant to an underwriting agreement with Canaccord Genuity at a price of \$20.04 per share. We received proceeds of \$73.4 million, net of related expenses, and intend to use the proceeds for working capital and general corporate purposes.

During 2010 we received 288,992 shares that were surrendered by employees in payment for the minimum required withholding taxes due on issuance of shares of our common stock under the 2009 Corporate Bonus Plan and vesting of restricted stock awards under the 2009 Performance Share Plan. Additionally, during 2010, we received 36,112 shares that were surrendered in payment for the exercise of

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stock options. These shares have been classified as treasury stock in the consolidated balance sheets. The settlement of the 2009 Corporate Bonus Plan obligation of \$1.6 million during the first quarter of 2010 in shares of our common stock represents a noncash financing activity.

In May 2008, we entered into a \$43.0 million private placement agreement to sell an aggregate of 9.6 million shares of our common stock at a price of \$4.50 per share and warrants to purchase 1.9 million shares of our common stock at an exercise price of \$5.50 per share to certain accredited investors managed by a single advisor, OrbiMed Advisors LLC, and other affiliates, including a member of the Company's board of directors. The private placement took place in two closings, on May 28, 2008 and August 1, 2008. The proceeds from both tranches, net of transaction costs, were approximately \$42.3 million.

We are required to register the common stock and the common stock issuable upon exercise of the warrants with the Securities and Exchange Commission, which was done on August 8, 2008. If the holders of the shares or the accompanying warrant shares are unable to sell such shares or warrant shares under the registration statement for more than 30 days in any 365 day period after the effectiveness of the registration statement, we may be obligated to pay damages equal to up to 1% of the share purchase price per month that the registration statement is not effective and the investors are unable to sell their shares.

The fair value of the warrants at issuance was \$5.1 million and was recorded as a liability on our consolidated balance sheet and in equity as a reduction of the total proceeds received from the transaction. We recognized a \$3.2 million gain in other expense during 2008 related to changes in fair value of outstanding warrants. These amounts were determined using the Black-Scholes option pricing model and calculated using the following assumptions: 67% volatility; expected term of 5 years; 1.6% — 3.4% risk-free interest rate; and 0% dividend. The fair value of the warrants issued in connection with the private placement represents a noncash financing activity.

The exercise price of the warrants to purchase shares of our common stock issued in connection with this private placement was fixed at \$5.50 per share on December 31, 2008 based on our achievement of over 3,100 ESRD patients prescribed to receive therapy using the System One. As a result, the fair value of these warrants of \$1.9 million at December 31, 2008 was reclassified from a current liability to equity on January 1, 2009. The reclassification on January 1, 2009 represents a noncash financing activity. The warrants have a term of 5 years and expire on May 28, 2013 and August 1, 2013 for the first and second tranches, respectively. The warrants also contain a net share settlement feature that is available to investors once the underlying shares are registered. Additional provisions require us, in the event of a change of control, to pay promptly to the warrant holder an amount calculated by the Black-Scholes option pricing formula. Such payment is required to be in cash or shares in the same proportion that other stockholders receive in such change of control transaction. As of December 31, 2010, 1.6 million warrants are outstanding and expire on May 28, 2013 or August 1, 2013.

Our obligation to issue the second tranche in the May 2008 private placement met the definition of a derivative instrument under ASC 815. We recognized a \$0.7 million loss during 2008 related to the fair value of this derivative instrument upon settlement, which was recorded in other expenses and in equity as a reduction of the total proceeds received from the transaction. This amount was determined using the Black-Scholes option pricing model and calculated using the following assumptions: 76% volatility; expected term of 32 days; 1.9% risk-free interest rate; and 0% dividend. The fair value of the derivative instrument issued in connection with the private placement represents a noncash financing activity.

16. Related-Party Transactions

On June 4, 2007, we entered into a stock purchase agreement with David S. Utterberg, a director and significant stockholder, under which we agreed to purchase from Mr. Utterberg the issued and outstanding shares of Medisystems Corporation and certain affiliated entities in exchange for the issuance of 6.5 million

NXSTAGE MEDICAL, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

shares of our common stock. We may be required to issue additional shares of common stock to Mr. Utterberg because, pursuant to the terms of the stock purchase agreement, Mr. Utterberg and we have agreed to indemnify each other in the event of certain breaches or failures, and any such indemnification amounts must be paid in shares of our common stock, valued at the time of payment. However, we will not be required to issue shares for indemnification purposes that in the aggregate would exceed 20% of the then outstanding shares of our common stock without first obtaining stockholder approval, and any such shares will not be registered under the Securities Act of 1933, as amended. In connection with the acquisition of Medisystems, we assumed a \$2.8 million liability owed to Lifestream Medical Corporation, a Nevada corporation (formerly known as DSU Medical Corporation), which is wholly-owned by Mr. Utterberg. We paid the liability during 2008. As a condition to the parties' obligations to consummate the Medisystems acquisition, Mr. Utterberg and Lifestream Medical Corporation entered into a consulting agreement with us, dated October 1, 2007. We paid Mr. Utterberg and Lifestream Medical Corporation \$150,000 and \$200,000 during 2009 and 2008, respectively, in consideration for services performed under this agreement. Finally, in connection with the Medisystems acquisition, we also agreed that if Mr. Utterberg is no longer a director of NxStage, our Board of Directors will nominate for election to our Board of Directors any director nominee proposed by Mr. Utterberg, subject to certain conditions.

In May 2008, we entered into Securities Purchase Agreements relating to a \$43.0 million private placement of shares of our common stock and warrants to purchase shares of our common stock. The private placement took place in two closings, on May 28, 2008 and August 1, 2008. Participants in the private placement consisted of unaffiliated and affiliated accredited institutional investors. One of these investors, the Sprout Group, is affiliated with one of our Board members, Dr. Philippe O. Chambon. The Sprout Group purchased 1.0 million shares and warrants to purchase 0.2 million shares of our common stock at a price similar to that of unaffiliated investors. Under applicable rules of the NASDAQ Global Market, the second closing of the private placement, which included all shares issued to the Sprout Group and other affiliated accredited institutional investors, was subject to stockholder approval, which was obtained at a special meeting on July 31, 2008.

We entered into a Securities Purchase Agreement with OrbiMed Advisors, LLC, or OrbiMed, in connection with the private placement which required that we appoint one individual nominated by OrbiMed to our Board of Directors upon the earlier of the second closing of the private placement or sixty days after the first closing of the private placement. The appointment of Mr. Jonathan Silverstein, a general partner of OrbiMed, on July 23, 2008, to the Board satisfied this requirement. OrbiMed purchased an aggregate of 5.6 million shares and warrants to purchase 1.1 million shares of our common stock in connection with the private placement at a price similar to that of unaffiliated investors. Mr. Silverstein subsequently resigned from our Board on January 20, 2011.

17. Fair Value Measurements

At December 31, 2010, we had \$84.8 million in money market funds, included in cash and cash equivalents, measured at fair value on a recurring basis utilizing quoted prices (unadjusted) in active markets of identical assets, also referred to as level 1 inputs.

The carrying amounts reflected in the consolidated balance sheets for cash, accounts receivable, prepaids and other current and non-current assets, accounts payable and accrued expenses approximate fair value due to their short-term nature.

The carrying amount of our long-term debt approximates fair value at December 31, 2010. The fair value of our long-term debt was estimated using inputs derived principally from market observable data, including current rates offered to us for debt of the same or similar remaining maturities. Within the hierarchy of fair value measurements, these are level 2 inputs.

NXSTAGE MEDICAL, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS — (Continued)

18. Quarterly Financial Data (Unaudited)

The following table sets forth selected quarterly information (unaudited) (in thousands, except per share data):

	Three Months Ended			
	March 31, 2010	June 30, 2010	September 30, 2010	December 31, 2010
Revenues	\$40,408	\$44,008	\$45,033	\$49,769
Gross profit(1)	11,813	13,762	14,960	17,592
Net loss	(8,999)	(8,256)	(8,164)	(6,293)
Net loss per common share, basic and diluted	\$ (0.19)	\$ (0.17)	\$ (0.17)	\$ (0.13)

	Three Months Ended			
	March 31, 2009	June 30, 2009	September 30, 2009	December 31, 2009
Revenues	\$ 33,735	\$ 36,398	\$ 38,033	\$40,510
Gross profit	7,055	8,817	9,545	11,447
Net loss(2)	(12,228)	(12,515)	(10,047)	(8,677)
Net loss per common share, basic and diluted	\$ (0.26)	\$ (0.27)	\$ (0.22)	\$ (0.19)

- (1) During the fourth quarter of 2010, we changed the estimated useful life of certain of our field equipment assets from five to seven years which resulted in a reduction in costs of revenues of \$0.5 million during the three months ended December 31, 2010.
- (2) During the three months ended June 30, 2009, we incurred prepayment and other transaction fees of \$2.0 million, which were recorded to interest expense, to pay off the entire debt obligation owed under our credit and security agreement with GE.

Item 9. *Changes in and Disagreements with Accountants on Accounting and Financial Disclosure*

None.

Item 9A. *Controls and Procedures*

Our management, with the participation of our chief executive officer and chief financial officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2010. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of NxStage’s disclosure controls and procedures as of December 31, 2010, our chief executive officer and chief financial officer concluded that, as of such date, NxStage’s disclosure controls and procedures were effective at the reasonable assurance level.

No change in NxStage’s internal control over financial reporting occurred during the fiscal quarter ended December 31, 2010 that has materially affected, or is reasonably likely to materially affect, NxStage’s internal control over financial reporting.

Management’s Report on Internal Control over Financial Reporting

We, as management of NxStage Medical, Inc., are responsible for establishing and maintaining adequate internal control over financial reporting. Pursuant to the rules and regulations of the Securities and Exchange Commission, internal control over financial reporting is a process designed by, or under the supervision of, the company’s principal executive and principal financial officer, or persons performing similar functions, and effected by the company’s board of directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

- Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;
- Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and
- Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on our financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Management has evaluated the effectiveness of its internal control over financial reporting as of December 31, 2010, based on the control criteria established in a report entitled Internal Control — Integrated Framework, issued by the Committee of Sponsoring Organizations of the Treadway Commission.

Based on such evaluation, we have concluded that NxStage's internal control over financial reporting is effective as of December 31, 2010.

The independent registered public accounting firm of Ernst & Young LLP, as auditors of NxStage's consolidated financial statements, has issued an attestation report on its assessment of NxStage's internal control over financial reporting.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders of NxStage Medical, Inc.

We have audited NxStage Medical, Inc.'s internal control over financial reporting as of December 31, 2010, based on criteria established in Internal Control — Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (the COSO criteria). NxStage Medical, Inc.'s management is responsible for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, NxStage Medical, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2010, based on the COSO criteria.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of NxStage Medical, Inc. as of December 31, 2010 and 2009, and the related consolidated statements of operations, changes in stockholders' equity, and cash flows for each of the three years in the period ended December 31, 2010, and our report dated February 18, 2011 expressed an unqualified opinion thereon.

/s/ Ernst & Young LLP

Boston, Massachusetts
February 18, 2011

Item 9B. Other Information

PART III

We have included information about our executive officers in Part I of the report under the caption "Executive Officers".

The information required by Part III, Items 10-14 of this report is incorporated by reference from our definitive proxy statement for our 2011 Annual Meeting of Stockholders. Such information will be contained in the sections of such proxy statement captioned "Stock Ownership of Certain Beneficial Owners and Management," "Proposal 1 — Election of Directors," "Corporate Governance," "Information about Executive Officer and Director Compensation," "Certain Relationships and Related Transactions," "Other Matters — Section 16(a) Beneficial Ownership Reporting Compliance".

Certain documents relating to the registrant's corporate governance, including the Code of Business Conduct and Ethics, which is applicable to the registrant's directors, officers and employees and the charters of the Audit Committee, Compensation Committee and Nominating and Corporate Governance Committee of the registrant's Board of Directors, are available on the registrant's website at <http://www.nxstage.com>.

PART IV

Item 15. Exhibits, Financial Statement Schedules

(a) *Financial Statements*

The following consolidated financial statements are filed as part of this Annual Report under "Item 8 — Financial Statements and Supplementary Data":

Report of Independent Registered Public Accounting Firm	72
Consolidated Balance Sheets	73
Consolidated Statements of Operations	74
Consolidated Statements of Changes in Stockholders' Equity	75
Consolidated Statements of Cash Flows	76
Notes to Consolidated Financial Statements	77

(b) *Exhibits*

The exhibits listed in the Exhibit Index immediately preceding the exhibits are incorporated herein by reference and are filed as part of this Annual Report on Form 10-K.

(c) *Financial Statement Schedules*

None. No financial statement schedules have been filed as part of this Annual Report on Form 10-K because they are either not applicable or the required information has been included in the accompanying notes to the consolidated financial statements.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this Annual Report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized.

NXSTAGE MEDICAL, INC.

By: /s/ Jeffrey H. Burbank

Jeffrey H. Burbank
President and Chief Executive Officer
February 18, 2011

Pursuant to the requirements of the Securities Exchange Act of 1934, this Annual Report on Form 10-K has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Jeffrey H. Burbank</u> Jeffrey H. Burbank	President, Chief Executive Officer and Director	February 18, 2011
<u>/s/ Robert S. Brown</u> Robert S. Brown	Chief Financial Officer and Senior Vice President (Principal Financial and Accounting Officer)	February 18, 2011
<u>/s/ Philippe O. Chambon</u> Philippe O. Chambon, M.D., Ph.D.	Chairman of the Board of Directors	February 18, 2011
<u>/s/ Daniel A. Giannini</u> Daniel A. Giannini	Director	February 18, 2011
<u>/s/ Craig W. Moore</u> Craig W. Moore	Director	February 18, 2011
<u>/s/ Reid Perper</u> Reid Perper	Director	February 18, 2011
<u>/s/ Earl R. Lewis</u> Earl R. Lewis	Director	February 18, 2011
<u>/s/ Nancy J. Ham</u> Nancy J. Ham	Director	February 18, 2011
<u>/s/ David S. Utterberg</u> David S. Utterberg	Director	February 18, 2011

EXHIBIT INDEX

<u>Exhibit Number</u>	<u>Description</u>	<u>Form or Schedule</u>	<u>Incorporated by Reference to</u>		
			<u>Exhibit No.</u>	<u>Filing Date with SEC</u>	<u>SEC File Number</u>
3.1	Restated Certificate of Incorporation	S-1/A	3.4	10/7/2005	333-126711
3.2	Amended and Restated By-Laws	S-1/A	3.5	10/7/2005	333-126711
4.1	Specimen Certificate evidencing shares of common stock	S-1/A	4.1	10/7/2005	333-126711
4.2	Form of Securities Purchase Agreement, dated May 22, 2008 and a schedule of signatories thereto	8-K	4.1	5/23/2008	000-51567
4.3	Form of Warrant to Purchase Common Stock	8-K	4.2	5/23/2008	000-51567
10.1#	1999 Stock Option and Grant Plan, as amended	S-1/A	10.1	10/7/2005	333-126711
10.2#	Form of Incentive Stock Option Agreement under the 1999 Stock Option and Grant Plan, as amended	S-1/A	10.2	10/7/2005	333-126711
10.3#	Form of Nonstatutory Stock Option Agreement under the 1999 Stock Option and Grant Plan, as amended	S-1/A	10.3	10/7/2005	333-126711
10.4#	2005 Stock Incentive Plan, as amended by Amendment No. 1, together with Form of Incentive Stock Option Agreement, Form of Nonstatutory Stock Option Agreement and Form of Restricted Stock Agreement	10-Q S-1/A 10-K	10.3 10.22 10.5	11/7/2007 10/20/2005 3/16/2007	000-51567 333-126711 000-51567
10.5#	2005 Employee Stock Purchase Plan, as amended by Amendment No. 1	10-K	10.5	3/7/2008	000-51567
10.6#	Employment Agreement dated October 19, 2005 between the Registrant and Jeffrey H. Burbank	S-1/A	10.12	10/20/2005	333-126711
10.7#	Employment Agreement dated October 18, 2005 between the Registrant and Joseph E. Turk, Jr.	S-1/A	10.15	10/20/2005	333-126711
10.8#	Employment Agreement dated October 18, 2005 between the Registrant and Winifred L. Swan	S-1/A	10.16	10/20/2005	333-126711
10.9#	Employment Agreement dated November 27, 2006 between Registrant and Robert S. Brown	10-K	10.1	3/16/2007	000-51567
*10.10	Employment Agreement dated August 16, 2007 between Registrant and Michael J. Webb				
10.11#	Form of Indemnification Agreement entered into between the Registrant and each of its Directors and Executive Officers	S-1/A	10.21	9/21/2005	333-126711
10.12#	Summary of 2006 Executive Compensation and 2006 Corporate Bonus Plan				
10.13#	Director Compensation Policy	10-Q	10.2	5/5/2006	000-51567
10.14	Standard Form Commercial Lease dated October 17, 2000 between the Registrant and Heritage Place, LLC, as amended by Modification to Standard Form Commercial Lease	S-1	10.1	7/19/2005	333-126711
10.15†	Supply Agreement dated as of October 26, 2004 between the Registrant and B. Braun Medizintechnologie GmbH	S-1	10.17	7/19/2005	333-126711
10.16†	Supply Agreement dated as of January 5, 2007 between the Registrant and Membrana GmbH	10-K	10.27	3/16/2007	000-51567

<u>Exhibit Number</u>	<u>Description</u>	<u>Form or Schedule</u>	<u>Incorporated by Reference to</u>		
			<u>Exhibit No.</u>	<u>Filing Date with SEC</u>	<u>SEC File Number</u>
10.17†	First Amended and Restated National Service Provider Agreement dated as of July 22, 2010 between the Registrant and DaVita Inc.	10-Q	10.01	8/6/2010	000-51567
10.18†	Extracorporeal Disposables Distribution Agreement, dated July 25, 2007, by and between Medisystems Corporation and Henry Schein	10-Q	10.4	11/7/2007	000-51567
10.19†	Supply and Distribution Agreement, dated February 1, 2001 by and between Medisystems Corporation and Kawasumi Laboratories, Inc.	10-Q	10.6	11/7/2007	000-51567
10.20	Investors' Rights Agreement dated June 30, 1999 between the Registrant and the Investors, as amended on January 24, 2000, May 24, 2001, April 15, 2003, August 18, 2004, December 23, 2004 and July 8, 2005	S-1	10.9	7/19/2005	333-126711
10.21†	Needle Purchase Agreement, dated January 6, 2008, by and between the Registrant and DaVita Inc.	10-K	10.37	3/7/2008	000-51567
10.22†	Shelter Agreement, dated March 21, 2007 by and among the Registrant, Entrada Partners and Entrada Group de Mexico, S. de R.L. de C.V.	10-Q	10.6	5/9/2007	000-51567
10.23†	Supply and Distribution Agreement, dated May 6, 2008, by and between Medisystems Corporation and Kawasumi Laboratories, Inc.	10-Q	10.43	8/8/2008	000-51567
10.24†	Supply Agreement, dated April 10, 2009, by and between the Registrant and Laboratorios PiSA	10-Q/A	10.45	10/19/2009	000-51567
10.25†	Extracorporeal Disposables Distribution Agreement, dated June 15, 2009, by and between Medisystems Corporation and Gambro Renal Products, Inc.	10-Q	10.46	8/7/2009	000-51567
10.26†	Term Loan and Security Agreement effective June 5, 2009 by and between the Registrant, EIR Medical, Inc., Medisystems Services Corporation, Medisystems Corporation, as Borrowers, and Medimexico s. de R.L. de C.V., NxStage Verwaltungs GmbH, NxStage GmbH & Co. KG and Medisystems Europe S.p.A., as Guarantors and Asahi Kasei Kuraray Medical, Co., Ltd., as the Lender	10-Q	10.47	8/7/2009	000-51567
10.27†	Amendment, dated as of March 10, 2010, to the Term Loan and Security Agreement, effective June 5, 2009, by and between the Registrant, EIR Medical, Inc., Medisystems Services Corporation, Medisystems Corporation, as Borrowers, and Asahi Kasei Kuraray Medical, Co., Ltd., as the Lender	10-Q	10.49	5/5/2010	000-51567
10.28†	Technology and Trademark License Agreement effective June 15, 2009 by and between the Registrant and Asahi Kasei Kuraray Medical Co., Ltd.	10-Q	10.48	8/7/2009	000-51567

<u>Exhibit Number</u>	<u>Description</u>	<u>Form or Schedule</u>	<u>Incorporated by Reference to</u>		
			<u>Exhibit No.</u>	<u>Filing Date with SEC</u>	<u>SEC File Number</u>
10.29†	Loan and Security Agreement, dated March 10, 2010, by and among Silicon Valley Bank, as the Lender, and the Registrant, EIR Medical, Inc., Medisystems Corporation and Medisystems Services Corporation, as Borrowers	10-Q/A	10.48	7/22/2010	000-51567
10.30	Warrant to Purchase Shares of Common Stock, dated July 22, 2010, issued to DaVita Inc.	10-Q	10.2	8/6/2010	000-51567
10.31	Registration Rights Agreement, dated July 22, 2010, between the Registration and DaVita Inc.	10-Q	10.3	8/6/2010	000-51567
*21.1	List of Subsidiaries				
*23.1	Consent of Ernst & Young LLP				
*31.1	Certification of Chief Executive Officer pursuant to Exchange Act Rules 13a-14a or 15d-14a, as adopted pursuant to Section 302 of Sarbanes-Oxley Act of 2002				
*32.1	Certification of Chief Financial Officer pursuant to Exchange Act Rules 13a-14a or 15d-14a, as adopted pursuant to Section 302 of Sarbanes-Oxley Act of 2002				
*32.1	Certification of Chief Executive Officer pursuant to Exchange Act Rules 13a-14(b) or 15d-14(b) and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of Sarbanes-Oxley Act of 2002				
*32.2	Certification of Chief Financial Officer pursuant to Exchange Act Rules 13a-14(b) or 15d-14(b) and 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of Sarbanes-Oxley Act of 2002				

* Filed herewith.

† Confidential treatment requested as to certain portions, which portions are omitted and filed separately with the Securities and Exchange Commission.

Management contract or compensatory plan or arrangement filed as an Exhibit to this report pursuant to 15(a) and 15(c) of Form 10-K.

**CERTIFICATION PURSUANT TO RULE 13A-14(A)/15D-14(A),
AS ADOPTED PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Jeffrey H. Burbank, certify that:

1. I have reviewed this Annual Report on Form 10-K of NxStage Medical, Inc. for the fiscal year ended December 31, 2010 (this "report");
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)), and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls over financial reporting.

/s/ Jeffrey H. Burbank

Jeffrey H. Burbank
President and Chief Executive Officer

Date: February 18, 2011-

**CERTIFICATION PURSUANT TO RULE 13A-14(A)/15D-14(A),
AS ADOPTED PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Robert S. Brown, certify that:

1. I have reviewed this Annual Report on Form 10-K of NxStage Medical, Inc. for the fiscal year ended December 31, 2010 (this "report");

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)), and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls over financial reporting.

/s/ Robert S. Brown

Robert S. Brown
Chief Financial Officer and Senior Vice President

Date: February 18, 2011

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report on Form 10-K of NxStage Medical, Inc. (the "Company") for the year ended December 31, 2010 as filed with the Securities and Exchange Commission on the date hereof (this "report"), I, Jeffrey H. Burbank, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

- (1) This report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in this report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Jeffrey H. Burbank _____

Jeffrey H. Burbank
President and Chief Executive Officer

Date: February 18, 2011

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report on Form 10-K of NxStage Medical, Inc. (the "Company") for the year ended December 31, 2010 as filed with the Securities and Exchange Commission on the date hereof (this "report"), I, Robert S. Brown, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

- (1) This report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) The information contained in this report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Robert S. Brown

Robert S. Brown
Chief Financial Officer and Senior Vice President

Date: February 18, 2011

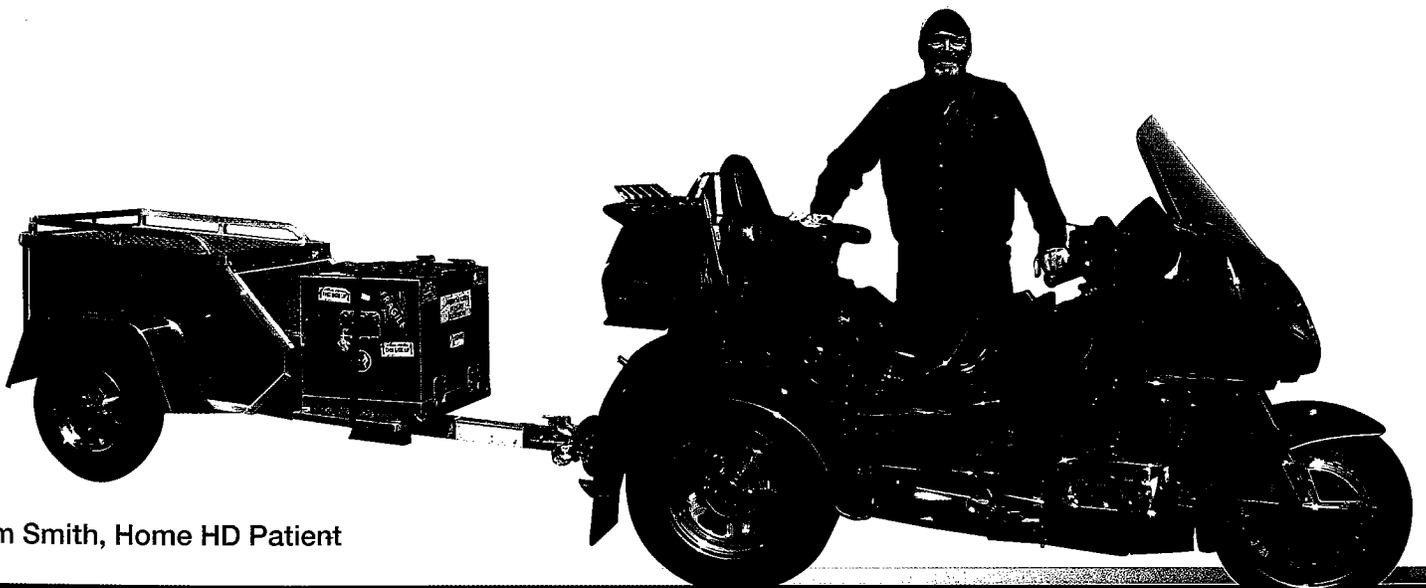
NOTES

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When Jim's kidneys failed in 2007, he began treatments in-center. The treatment schedule caused him to cut back on some of his hours as a salesman, which involved a changeable schedule and much travel. But the most significant motivation to learn to do dialysis at home was personal independence.

I wanted to be able to say when and where I'd do treatments.



— Jim Smith, Home HD Patient



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www.nxstage.com